UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

In the Matter of	)	
Schering-Plough Corporation, a corporation,	)	Docket No. 9297
Upsher-Smith Laboratories, Inc. a corporation,	)	
and	)	
American Home Products Corporation, a corporation.	)	

AMERICAN HOME PRODUCTS CORPORATION'S REPLY MEMORANDUM IN SUPPORT OF ITS MOTION TO COMPEL COMPLAINT COUNSEL TO CONFINE THEIR THEORIES TO THE ALLEGATIONS IN THE COMPLAINT

The Commission has held that when it makes a "conscious choice of . . . particular complaint language," complaint counsel are authorized to try the case only on the basis of that language. In re Beatrice Foods Co., 101 F.T.C. 733, 826 (1983). As the Commission has explained:

> In its dual role as prosecutor and judge, the Commission has a special obligation, different from that of ordinary courts of law, to maintain effective control over the purpose, construction, and adjudication of the complaints it issues. Rule 3.15(a)(1) was placed on the books to facilitate the Commission's exercise of such control. To allow new theories to be added, provided only that the respondent has adequate notice and an opportunity to litigate the issues, would defeat the very purpose of this important safeguard in our rules, and undermine the Commission's control over its prosecutorial discretion.

Id. at 827. Rule 3.15(a)(1) gives complaint counsel a straightforward way to attempt to try a case other than one based on the particular complaint's language: file a motion to amend the

complaint, which is then certified to the Commission. In their response to AHP's Motion to Confine, however, complaint counsel raise two new theories that deviate from the Commission's particular complaint language, and that clearly were not pled in the Commission's complaint. Yet they apparently have no intention of seeking to amend the complaint. Since complaint counsel have chosen not to file such a motion, this Court should order complaint counsel to try the case that the Commission authorized them to try.

AHP respectfully requests that the Court permit oral argument on AHP's Motion.

I. COMPLAINT COUNSEL'S NEW THEORIES MATERIALLY DEVIATE FROM THE PLAIN LANGUAGE OF THE COMPLAINT

AHP's Motion was precipitated by complaint counsel's May 30 letter, in which complaint counsel purported to set forth a "theory of harm" that, in complaint counsel's own words, "expanded on" the allegations of the complaint.[1] Complaint counsel are now recanting their own characterization of the letter, but appear muddled as to exactly what their letter was intended to achieve. They now assert, on the one hand, that they intended merely to "clarify" the allegations in the complaint.[2] On the other hand, they also assert that they intended only to "identify[] additional facts" that they expect to prove.[3] Neither is an accurate characterization of what complaint counsel are doing.

Complaint counsel in fact are trying to deviate substantially from the Commission's complaint by interjecting new theories inconsistent with those in the complaint. The basic theory of the complaint, as described in detail in AHP's Motion, is that the anticompetitive

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[1] See May 30, 2001 Letter from Complaint Counsel to Counsel for AHP (attached as Exhibit 1 to AHP's Motion and Exhibit 1 to Complaint Counsel's Response) at 1 (emphasis added).

[2] Complaint Counsel's Response to AHP's Motion to Compel Complaint Counsel to Confine their Theories to the Allegations in the Complaint ("Response") at 5.

effect of the AHP/Schering agreement was caused by a delay in AHP's entry into the market from March 2002 until January 2004. It is this basic theory that complaint counsel are now trying to repudiate.

A. The New "Legal Uncertainties" Theory is Inconsistent with the Complaint

The new theory that complaint counsel raised in their May 30 letter, and which, with the exception of one remarkable footnote, is the only theory discussed in their Response, is premised on so-called "legal uncertainties" that complaint counsel claim existed in January 1998, when AHP and Schering entered into a tentative agreement licensing AHP to begin selling generic K-Dur 20 in January 2004. Complaint counsel assert that because of those "legal uncertainties," in January 1998 there was "a significant possibility that AHP might be able to enter the market before March 2002." Response at 3. Those "uncertainties," they say, affected the length of delay of AHP's entry into the market. Id. at 6. Thus, they now appear to be saying that the AHP/Schering agreement delayed AHP's entry into the market from sometime before March 2002 until January 2004. They argue that since the complaint need not even plead how long the delay was, they do not have to seek to amend the complaint just because they are now identifying how long the delay was. Id. at 6 n.7.

What complaint counsel must and fail to do, however, is reconcile their new theory with the "particular complaint language" that the Commission chose. It is one thing for complaint counsel to identify the "length of delay" when no period of delay is specified in the complaint. It is quite another to reject the period of delay the Commission chose to

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[3] Id. at 6-7 (emphasis added).

specify (i.e., March 2002 to January 2004), on the basis of theories nowhere articulated in the complaint.[4]

The Commission's complaint flatly rejects both the premise of complaint counsel's new theory – that there were "legal uncertainties" in January 1998 that made it unclear whether AHP was blocked from entering – and the conclusion – that there was "a significant possibility that AHP might be able to enter the market before March 2002." The complaint states in no uncertain terms that "at all times relevant herein, FDA final approval of an ANDA for a generic version of K-Dur 20 for anyone other than Upsher-Smith was blocked." Complaint ¶ 29.

Complaint counsel's only attempt to reconcile their theory with the complaint is to try to torture the language of the complaint to be consistent with their new theory. Buried in a footnote on the last page of their Response, complaint counsel say that "at all relevant times," as used in Paragraph 29 of the complaint, does not mean in January 1998. Response at 7 n.8. This is a "strained interpretation of the reasonably clear meaning and intent" of the phrase, as the Commission said in Beatrice Foods when it rejected complaint counsel's attempt to interject a new theory that was inconsistent with the complaint. Beatrice Foods, 101 F.T.C. at 827. Complaint counsel state elsewhere that "the critical time to analyze the import of the [AHP/Schering] agreements is January 1998." Response at 5 n.5. It strains credulity to argue that the Commission, in asserting a critical allegation applicable to "all times relevant herein," meant all times except the "critical" time. If complaint counsel's fanciful interpretation of "at all times relevant" were accepted, what then should respondents make of

[4] The four cases complaint cite for the proposition that they need not seek to amend the complaint, in which the ALJs denied motions for more definite statements, have nothing to do with the circumstances present here,

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the allegations that precede and follow Paragraph 29 -- that "[a]t all times relevant herein, entry into the relevant markets was restricted and unlikely to diminish Schering's market share[,]" and that "[a]t all times relevant herein, the existence of generic versions of branded potassium chloride supplements other than K-Dur 20 has not constrained Schering's market power in the potassium chloride supplement market"? Complaint ¶¶ 28, 30 (emphases added). Are these allegations likewise applicable only to some unidentified period that does not encompass the time at which AHP and Schering entered into their tentative agreement? We suspect not. The meaning and intent of the phrase "at all times relevant herein" can not be construed, as complaint counsel would have it, to mean something different, and unspecified, each time it is used. Nor is there any indication in the Complaint that the Commission intended such a tortured result.

B. The New "Possibility of Litigating and Prevailing" Theory is Inconsistent with the Complaint

Not content to advance one new theory inconsistent with and not pled in the complaint, complaint counsel's Response raises yet another new theory that contradicts the complaint's allegations that AHP was blocked from entering the market until March 2002. In a footnote, complaint counsel make the astonishing assertion that "it was possible that AHP could enter before March 2002 if it continued to litigate and prevail." Response at 4 n.4. Although the assertion is left unexplained and relegated to a footnote, it is plain, based on complaint counsel's interrogatory responses, their Opposition to Upsher-Smith's Motion to Dismiss, and the reports of their experts, that this theory is now going to be a linchpin of

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because none of them involved a change to a time period the Commission had specified in the complaint. See Response at 2 n.1 and 6 n.7.

complaint counsel's trial of this case. Again, however, the theory is flatly inconsistent with the case the Commission authorized them to try.

Complaint counsel's latest attempt to insist, contrary to the complaint, that AHP could have entered the market before March 2002, is based on the provisions of the Hatch-Waxman statute that confer 180 days of market exclusivity to the first generic manufacturer to file an Abbreviated New Drug Application (ANDA).[5] Pursuant to the statute, two events can trigger the start of an ANDA first filer's 180-day exclusivity period: (1) the first filer's beginning to market its generic product or (2) a court decision that the pioneer company's patent is either invalid or not infringed. See 21 U.S.C. § 355(j)(5)(B)(iv)(I) and (II). According to the interpretation of the statute applicable at the time of AHP's settlement with Schering, the only court that could trigger the first filer's exclusivity period was the court in which the patent holder sued the first filer for patent infringement. See Appendix A.

Complaint counsel's opaque statement in footnote 4 of its Response – that AHP could have entered before March 2002 if it continued to litigate and prevail – is based on an interpretation of Hatch-Waxman under which the court decision required to trigger the first filer's exclusivity period did not need to be from the court where the first filer and the patent holder were litigating. Under complaint counsel's interpretation, "any court" could trigger

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[5] The applicable provisions of the Hatch-Waxman statute may be found at 21 U.S.C. § 355(j)(5)(B)(iv) and read as follows:

> (iv) If the [ANDA] contains a certification described in [Paragraph IV] and is for a drug for which a previous application has been submitted under this subsection [containing a Paragraph IV] certification, the application shall be made effective not earlier than one hundred and eighty days after—
>
> (I) the date the Secretary receives notice from the applicant under the previous [ANDA] of the first commercial marketing of the drug under the previous [ANDA], or
>
> (II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed, whichever is earlier.

the first filer's exclusivity period by deciding that a subsequent generic manufacturer did not infringe the patent blocking the first filer (or by deciding that the same patent was invalid). In other words, a subsequent ANDA filer could win its infringement suit and thereby "trigger" the beginning of the first filer's exclusivity period, irrespective of what was going on in the first filer's infringement litigation with the patent holder. Thus, complaint counsel are now saying that AHP could have kept on litigating the patent infringement case with Schering, could have won that litigation, could thereby have triggered the start of Upsher-Smith's exclusivity period before September 2001, and therefore could have entered the market before March 2002.

For the reasons we outline in Appendix A, complaint counsel's theory is flat out wrong, because it is based on an interpretation of Hatch-Waxman that was not established law at the time of AHP's tentative settlement with Schering.[6] More fundamentally, however, this latest elaborate theory is nowhere to be found in the Commission's complaint and again, contradicts the Commission's allegations that AHP was blocked from entering the market until March 2002. The Commission did not allege that AHP could have litigated and prevailed, nor did it allege that AHP could thereby have triggered the start of Upsher-Smith's exclusivity period. The Commission most assuredly did not allege that AHP could thereby have entered the market before March 2002. In fact it alleged the opposite. See, e.g., Complaint ¶¶ 29, 66.

[6] Indeed, while complaint counsel insist that January 1998 is "the critical time to analyze the import of the [AHP/Schering] agreement" (Response at 5 n.5), the only authority they cite for the proposition that as of January 1998 AHP could have triggered Upsher's exclusivity by litigating and prevailing is a court opinion issued in April 1998. See Response at 4 n.4.

II. COMPLAINT COUNSEL'S NEW THEORIES MATERIALLY DEVIATE FROM COMMISSIONER STATEMENTS AND GUIDANCE

Beyond being contrary to the express language of the complaint, complaint counsel's notion that as of January 1998 AHP could have entered the market before March 2002 by litigating, prevailing, and triggering Upsher's exclusivity period before September 2001 contradicts numerous statements that Commissioners have made about the correct interpretation of Hatch-Waxman. If there were any ambiguity in the language of the complaint – which we believe there is not – these authoritative statements by three of the voting Commissioners eliminate any ambiguity and confirm the plain meaning of the complaint: AHP was blocked from entering until the end of Upsher's exclusivity period in March 2002 and could not have triggered the start of that exclusivity period by litigating and prevailing.

During the course of 2000 and 2001, three Commissioners made public statements indicating their belief that the correct interpretation of Hatch-Waxman at the time of the AHP/Schering settlement was that a second ANDA filer like AHP could not trigger the start of the first filer's exclusivity period by litigating and prevailing. The Commissioners' statements about Hatch-Waxman were made in the context of publicly discussing two other FTC actions challenging agreements between pioneer and generic drug manufacturers. One of the agreements, between Hoechst and Andrx, occurred on or around September 24, 1997. The other, between Abbott and Geneva, took place on or around April 1, 1998. With respect to the state of the law concerning Hatch-Waxman exclusivity, both of these agreements therefore were contemporaneous to the AHP/Schering agreement.

In their statements interpreting the Hatch-Waxman statute in the context of these two actions, the three Commissioners repeatedly and consistently rejected the notion that, as of

the time of AHP's settlement, a subsequent ANDA filer could deprive the first filer of its exclusivity rights by triggering the first filer's 180-day period. Former Chairman Pitofsky, for example, stated just a few weeks before the complaint in this matter was issued:

> The agreements [in both Abbott-Geneva and Hoechst-Andrx] thus acted as corks in a bottle, precluding competition not only by the generic company that was paid not to challenge the branded pharmaceutical, **but also by other potential generic competitors because the 180 day period does not begin to run until the generic comes to market.**

Robert Pitofsky, Antitrust and Intellectual Property: Unresolved Issues at the Heart of the New Economy, Remarks before the Berkeley Center for Law and Technology "Antitrust, Technology and Intellectual Property" Conference, Berkeley, CA (March 2, 2001), at ¶ 30 (emphasis added); see also id. at ¶ 31 ("By staying out [of the market, a first filing generic acts] to preclude others from entering the market.").

Commissioner Leary was equally clear about the prevailing interpretation of the Hatch-Waxman during the relevant time period. In November 2000, he stated:

> Since Geneva's [the first ANDA filer] **agreement not to launch its product meant that the 180-day exclusivity period would not expire**, the effect of this provision in the agreement was to ensure that no other company's generic terazosin HCL product could obtain FDA approval and enter the market during the term of the agreement.

Thomas B. Leary, Antitrust Issues in Settlement of Pharmaceutical Patent Disputes, Remarks before the Northwestern University School of Law Sixth Annual Health Care Antitrust Forum, Chicago, IL (Nov. 3, 2000), at ¶¶ 26 (emphasis added).[7]

[7] In a footnote in his prepared remarks, Commissioner Leary acknowledged that the FDA issued proposed regulations that would allow for a subsequent filer to trigger the first filer's exclusivity period – but not until August 1999, well over a year after AHP and Schering had executed their agreement. See Thomas B. Leary, Antitrust Issues in Settlement of Pharmaceutical Patent Disputes, Remarks before the Northwestern University School of Law Sixth Annual Health Care Antitrust Forum, Chicago, IL (Nov. 3, 2000), at n.23 ("The FDA has proposed a new rule that would allow subsequent ANDA filers to trigger the 180-day exclusivity period in certain circumstances. See FDA Proposed Rule Regarding 180-Day Generic Drug Exclusivity for Abbreviated

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Commissioner Anthony articulated the same interpretation of the Hatch-Waxman statute when she stated that, "Geneva's agreement to neither use nor relinquish its 180-day exclusivity rights also **served to block any other potential entrants.**" Sheila F. Anthony, Riddles and Lessons from the Prescription Drug Wars: Antitrust Implications of Certain Types of Agreements Involving Intellectual Property, Remarks before the ABA "Antitrust and Intellectual Property: The Crossroads" Program, San Francisco, CA (June 1, 2000), at ¶ 17 (emphasis added); see also id. at ¶ 22 (An agreement not to transfer or relinquish exclusivity "kept any other would-be entrants from coming to market.").

The language of the complaint is consistent with these views expressed by three of the voting Commissioners: the complaint indicates that AHP was blocked from entering until March 2002, and states nowhere that AHP could have removed that block by litigating and prevailing.

III. THE NEW THEORIES CANNOT BE PURSUED WITHOUT COMMISSION APPROVAL

Complaint counsel's arguments about why they need not seek Commission approval to amend the complaint distort both what complaint counsel are doing in asserting these new theories and the case law.

First, complaint counsel argue that they need not seek to amend the complaint by motion to the Commission when all they are doing is to clarify the allegations. Response at 5, citing Century 21 Commodore Plaza Inc., 89 F.T.C. 238, 239 (1977). It is true that Century 21 stated that the ALJ may permit amendments that merely clarify allegations of the

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New Drug Applications, 64 Fed. Reg. 42873 (to be codified at 21 C.F.R. pt. 314.107) (proposed Aug. 6, 1999).").

complaint. In that case, however, the Commission held that complaint counsel's attempt to add an allegation that respondents, charged with deceptive advertising, did not have a reasonable basis for their advertising claims, must be certified to the Commission because it was not just an attempt to clarify the complaint. If that proposed allegation – which certainly could be deemed implicit in the nature of a deceptive advertising case – was not a clarification, then surely complaint counsel's outright rejection of the Commission's complaint language here can not constitute a "clarification" as to which this Court is permitted to allow complaint counsel to proceed.

Second, complaint counsel argue that Standard Camera, 63 F.T.C. 1238 (1963), which vacated the ALJ's decision to permit an amendment as being beyond the power of the ALJ, is not applicable here because in that case, the facts necessary to prove complaint counsel's new theory were different from the facts necessary to prove the complaint's theory. Response at 5-6. While we do not believe complaint counsel accurately characterize the basis of the Standard Camera decision, even if we assume that they do, it is likewise true here that the facts necessary to prove complaint counsel's new theories are different from the facts necessary to prove the complaint's theory. Under the complaint's theory, no issue is raised as to whether AHP could have entered the market prior to March 2002, and no evidence need be offered on that point by complaint counsel or AHP -- AHP would stipulate to the complaint's allegation that it was blocked from entering until March 2002, and indeed, has already so admitted in its answer to the complaint. But complaint counsel's new theories raise hosts of issues that will require the parties to put on evidence and argue about whether AHP could have – or more likely than not would have, as we believe the right standard to be -- entered at any time before March 2002.

Finally, complaint counsel do not even attempt to address the Commission's holding in Beatrice Foods, 101 F.T.C. 733 (1983), except in an oblique footnote parenthetical reference that does not address the substance of the case. See Response at 6 n.6. As described in AHP's Motion, Beatrice Foods held that complaint counsel could not, without seeking Commission authorization, pursue an unpled potential competition theory in addition to the actual competition theory that had been pled. There is no material difference between what complaint counsel did in Beatrice Foods and what they are attempting to do here.

Complaint counsel now are trying to prove a violation of Section 5 based only on ephemeral "possibilities" unmentioned in the Commission's complaint. With respect to complaint counsel's first new theory – that legal uncertainties about the successful defense requirement in January 1998 raised the "possibility" that AHP could have entered before March 2002 -- we question whether the Commission would find reason to believe that a violation of Section 5 had been committed simply because under one possible interpretation of the law, which the courts rejected, AHP could have entered the market before March 2002. With respect to complaint counsel's second new theory -- that AHP could have continued litigating, could have prevailed, could have thereby triggered Upsher's exclusivity period, and could have done all this before September 2001 – we question whether the Commission would accept such an attenuated theory of harm, particularly because that chain of events could not have occurred under then-prevailing interpretations of the law. Certainly nothing in the complaint alleges this convoluted theory. But these questions are for the Commission to resolve, not, respectfully, for this Court, and certainly not for complaint counsel. It would be a waste of this Court's, the parties', and the Commission's resources to permit complaint counsel to try a case that the Commission has not authorized. To avoid that wasteful

expenditure of resources, complaint counsel need only file a motion seeking the Commission's authorization to amend the complaint.

CONCLUSION

Given that complaint counsel's new theories require approval by the Commission before they may be pursued, and given that complaint counsel apparently have no intention of seeking Commission approval, the Court should order complaint counsel not to pursue – whether by argument or introduction of evidence – any theory that contradicts the allegation of the complaint that AHP was and is blocked from entering the market with its generic K-Dur 20 until March 2002.

AHP respectfully requests that the Court permit oral argument on AHP's Motion.

Respectfully submitted,

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Counsel for American Home Products Corporation

Dated: August 24, 2001

CERTIFICATE OF SERVICE

I hereby certify that this 24th day of August, 2001, I caused an original, one paper copy and an electronic copy of the following documents to be filed with the Secretary of the Commission:

American Home Products Corporation's Reply Memorandum In Support Of Its Motion To Compel Complaint Counsel To Confine Their Theories To The Allegations In The Complaint

Appendix A To American Home Products Corporation's Reply Memorandum In Support Of Its Motion To Compel Complaint Counsel To Confine Their Theories To The Allegations In The Complaint

I hereby certify that this 24th day of August, 2001, I also caused an original and one paper copy of the following document to be filed with the Secretary of the Commission:

Exhibits To Appendix A Of American Home Products Corporation's Reply Memorandum In Support Of Its Motion To Compel Complaint Counsel To Confine Their Theories To The Allegations In The Complaint

In addition, I certify that this 24th day of August, 2001, I caused two paper copies of all the above documents to be served by hand upon:

Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
600 Pennsylvania Avenue, NW
Room 104
Washington, D.C. 20580

and one paper copy of the above documents to be served via hand delivery upon each person listed below:

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UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

In the Matter of	)	
Schering-Plough Corporation, a corporation,	)	Docket No. 9297
Upsher-Smith Laboratories, Inc. a corporation,	)	
and	)	
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APPENDIX A TO
AMERICAN HOME PRODUCTS CORPORATION'S
REPLY MEMORANDUM IN SUPPORT OF ITS
MOTION TO COMPEL COMPLAINT COUNSEL TO CONFINE THEIR
THEORIES TO THE ALLEGATIONS IN THE COMPLAINT

Complaint counsel state in their Response that "even if Upsher-Smith did not lose exclusivity by settling, it was 'possible' that AHP could enter before March 2002 if it continued to litigate and prevailed. Such a decision would trigger Upsher-Smith's exclusivity." Response at 4 n.4. Complaint counsel's theory is based on an interpretation of the provision of the Hatch-Waxman statute that establishes the circumstances under which an ANDA first filer's 180-day exclusivity period will begin. The statute provides only two potential "triggers" for the 180-day period: (1) the first filer's beginning to market its generic product or (2) a court decision that the pioneer company's patent is either invalid or not infringed. See 21 U.S.C. § 355(j)(5)(B)(iv)(I) and (II). According to the interpretation of the statute prevailing at the time of AHP's settlement, the only court with the power to trigger the first filer's exclusivity period was the court hearing the

infringement action between the first filer and the patent holder. The FDA's 1994 regulations limited the "court decision" trigger to "the court" hearing the litigation between the first filer and the patent holder. See 21 C.F.R. § 314.107(c)(1)(ii).

According to complaint counsel's interpretation of the statute, however, "the court" triggering the first filer's exclusivity period can be "any court" deciding an infringement litigation between the patent holder and an ANDA filer whose generic product references the same brand name drug as the first filer's generic product. In other words, any subsequent ANDA filer can trigger the first filer's exclusivity period by obtaining a court ruling that the subsequent filer's generic product does not infringe the patent at issue (or that the patent is invalid). The only authority that complaint counsel cite for this interpretation is an April 1998 court decision issued months after the tentative agreement reached between AHP and Schering in January 1998, which complaint counsel say is "the critical time to analyze the import of the agreement." See Response at 4 n.4 and 5 n.5. Complaint counsel do not and can not point to any authority for the proposition that this interpretation was prevailing law as of January 1998.

HISTORY OF "ANY COURT" TRIGGER FOR HATCH-WAXMAN 180-DAY EXCLUSIVITY

Mova District Court Decision

The pertinent authority begins in January 1997, with Mova Pharmaceutical Corp. v. Shalala, 955 F. Supp. 128, 130 (D.D.C. 1997), aff'd, 140 F.3d 1060 (1998), where the district court adopted the first filer's contention that the "court decision" trigger could be satisfied only by a court victory in favor of the *first filer*:

> It is accordingly unlawful for FDA to approve Mylan's [the second filer's] ANDA until 180 days after (i) Mova [the first filer] begins commercially marketing its drug (which has not happened yet), or (ii) the

> court in Puerto Rico [hearing the first filer's case] holds the Upjohn patent invalid or not infringed (which also has not happened), whichever is earlier.

Mova, 955 F. Supp. at 130.[1] Indeed, the district court in Mova enjoined the FDA from approving any other generic manufacturers until either 180 days after the first filer began marketing or until 180 days after "the date of a decision in the U.S. District Court for the District of Puerto Rico holding that U.S. Patent No. 4,916,163 invalid or not infringed by [the first filer's] ANDA . . . ." Id. at 132.

FDA Experiments with "Any Court" Interpretation

Throughout ESI's patent infringement lawsuit against Schering, the FDA never issued a Policy, Guidance, or Federal Register Notice that contradicted the Mova court's injunction against the "any court" interpretation. In one isolated incident after Mova, however, the FDA did attempt to employ that interpretation. On June 17, 1997, the FDA sent approval letters to the manufacturers of generic ranitidine hydrochloride. In those letters, which were never published in any FDA Guidance, Policy, or Federal Register notice, the FDA informed the generic manufacturers that the first ANDA filer's exclusivity period for ranitidine would be measured in reference to a subsequent ANDA filer's court victory. See F-D-C Reports: "The Pink Sheet" at 3 (June 23, 1997), reprinted at 1997 WL 16952884.

Granutec District Court Decision

The first ANDA filer for generic ranitidine then sought an injunction prohibiting FDA from applying this interpretation. At oral argument, the district court criticized the

FDA for the manner in which it had allowed a subsequent ANDA filer to trigger the first filer's exclusivity period.[2] In a short, unpublished decision, the court granted the preliminary injunction against the FDA on the grounds that the FDA was required to follow its own regulations.[3] See Granutec, Inc. v. Shalala, 1997 WL 1403894 (E.D.N.C. July 3, 1997). Thus, both the Mova and Granutec district courts appeared to be in agreement that it was contrary to the statute to allow a subsequent filer to trigger the first filer's exclusivity period.

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[1] In Inwood Laboratories, Inc. v. Young, 723 F. Supp. 1523, 1527 (D.D.C. 1989), vacated as moot, 43 F.3d 712 (D.C. Cir. 1989), the FDA had also advocated a position that was inconsistent with the "any court" interpretation of Hatch-Waxman exclusivity.

[2] See Transcript of Hearing Before Hon. Terrence W. Boyle, Granutec, Inc. v. Shalala, No. 97-CV-485-BR (June 24, 1997), at 27, 58, & 62 (attached as Exhibit A). In addition to referring to the FDA's position as "ridiculous" and "totally illogical," see Exhibit A at 27 & 62, the following colloquy took place between the court and counsel for the first filer:

The Court:	So let me get this straight. The 180 days really isn't 180 days. It can't start before July 25th, is that what everybody agrees?
Counsel:	No. The FDA says it starts on March 3rd [the date of a subsequent filer's court victory].
The Court:	Uh-huh
Counsel:	So if we go to market on July 25th, we only get part of that 180 days.
The Court:	But yet they say it wasn't until June 17th that they told you had this 180-day right that started in March.
Counsel:	There is something strange about that.
The Court:	This is idiocy.
Counsel:	Your Honor, one of the things ---
The Court:	How could you have 180 days without knowing it and have it run against you?
Counsel:	Well, we tend to agree with Your Honor about that. And one of the things that we would like to be able to brief for the Court is the question of how to calculate properly that 180-day stay. We have, we believe, a potential disagreement with the FDA about that.

Exhibit A at 57-58.

FDA Retreats from its "Any Court" Experiment

The FDA's statements and conduct subsequent to June 17, 1997 suggested that the FDA was not likely to employ this interpretation of the statute again. First, after the Granutec district court opinion, the FDA retracted its June 17, 1997 interpretation of the statute en toto. See 62 Fed. Reg. 63,268, 63,269 (Nov. 1997). Second, in December 1997 and January 1998, the FDA filed its briefs in the Mova appeal in the D.C. Circuit, in which it acknowledged that the "any court" interpretation was not part of the FDA's regulatory scheme. The FDA argued that without the successful defense requirement, subsequent generics would not be allowed to enter the market at any time prior to patent expiration in the event that the first filer lost its infringement case against the pioneer. The FDA's argument was irreconcilable with the "any court" interpretation of the Hatch-Waxman statute. In its opening brief filed with the court on December 12, 1997, the FDA clearly stated that in the event the first filer lost the infringement suit filed against it by the pioneer, the first filer could not market until after the patent had expired, and no subsequent filer could market its product ahead of the first filer, even if the subsequent filer won the infringement suit against it:

> [W]hen the applicant loses the patent litigation, **there can be no trigger for exclusivity** under 21 U.S.C. 355(j)(4)(B)(iv)(II) because there is no court decision declaring the patent invalid or not infringed. The sole trigger for exclusivity, therefore, is the date of first commercial marketing under 21 U.S.C. 355(j)(4)(B)(iv)(I), and the earliest date for commercial marketing in the scenario where first paragraph IV filer loses the patent infringement suit is the expiration of the patent. . . . Even if they

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[3] The effect of the court's ruling was to require the FDA to enforce its "successful defense" requirement. This result was directly contrary to the Mova's court injunction which prohibited the FDA from enforcing the successful defense requirement.

> [subsequent filers] were to succeed in their patent infringement suits (for example, because they litigated better or had a different product that did not infringe the patent), they could not market their product ahead of the first filer.

Brief for the Federal Government (Dec. 12, 1997) at 19-20, Mova Pharmaceutical Corp. v. Shalala, 140 F.3d 1060 (D.C. Cir. 1998) (emphasis added) (attached as Exhibit B).

In its reply brief, filed January 22, 1998 (*before* ESI's tentative settlement), the FDA continued to press its argument that was irreconcilable with the "any court" interpretation:

> [I]f the first paragraph IV filer is always entitled to 180 days of market exclusivity, even when it loses its patent infringement suit, that loss means that no generic version of the pioneer drug can be marketed before the expiration of the patent at issue (plus 180 days for subsequent paragraph IV filers). . . . This is so, significantly enough, even if the subsequent paragraph filers ***win*** in their patent infringement litigation. (Subsequent filers might win because of better litigation or because they were able to design around the original patent. *See* Opening Br. at 20.) This is an absurd result and cannot be what Congress intended.

Reply Brief for the Federal Government at 6 (emphasis in original) (attached as Exhibit C); see also id. at 2 ("when the first paragraph IV filer loses its patent infringement suit – [it] –means that no generic drug can be marketed before the expiration of the patent at issue").

As an amicus in the Mova appeal, Teva Pharmaceuticals was permitted to submit a brief on the sole issue of the validity of the "any court" interpretation. As a subsequent filer in an unrelated matter, Teva argued strenuously in favor of the "any court" interpretation and attempted to persuade the D.C. Circuit to reverse that portion of the district court's opinion and order that had held that a subsequent filer could not trigger the first filer's exclusivity. See Brief for Teva Pharmaceuticals USA (Jan. 5, 1998) at 1-

2, Mova Pharmaceutical Corp. v. Shalala, 140 F.3d 1060 (D.C. Cir. 1998) (attached as Exhibit D).[4]

The FDA refused to support Teva's argument in favor of the "any court" interpretation. Instead, in a passage that appears to disavow its utilization of the "any court" interpretation six months earlier, in the June 17, 1997 ranitidine decision, the FDA stated:

> Teva argues that the statute should be interpreted to permit the subsequent filer, if not sued for patent infringement by the NDA holder, to begin marketing 180 days after its succeeds in a declaratory judgment action declaring the patent invalid or not infringed no matter the status of the first filer's patent infringement suit. (Teva says the same should apply even when the subsequent filer is sued for patent infringement and wins before the first filer's suit is concluded.) **FDA has not previously addressed this interpretation** and [sic] is not directly presented by the facts of the instant case. Therefore, the Court need not address the validity *vel non* of this interpretation at this time . . .

Reply Brief for the Federal Government (Exhibit C) at 12 (emphasis added) (citations omitted).

The FDA's statements to the D.C. Circuit in Mova are consistent with its decision to refrain from adopting its isolated June 17, 1997 experiment with complaint counsel's interpretation as its official policy or position with respect the Hatch-Waxman statute. It is also consistent with the FDA's decision not to publish its isolated June 17, 1997 decision in the Federal Register or in any Guidance to the industry.

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[4] Teva's brief began: "Teva Pharmaceuticals, USA ('Teva') respectfully submits this Brief, amicus curiae, seeking reversal of one aspect of the district court's preliminary injunction, in which it ordered that the Food and Drug Administration (FDA) suspend its approval of Mylan's Abbreviated New Drug Application ("ANDA") for the generic drug micronized glyburide. Specifically, the court erroneously ordered that the statutory bar to FDA approval of Mylan's ANDA could only be terminated 180 days after a decision of non-infringement in a patent infringement case pending in the United States District Court for the District of Puerto Rico between the patent holder Pharmacia & Upjohn Company ('Upjohn') and respondent Mova Pharmaceutical Corp. ('Mova')." Exhibit D at 1-2.

DC Circuit and District Court Confirm Invalidity of "Any Court"

Despite Teva's request, the D.C. Circuit did not endorse the "any court" interpretation of the statute. While the court found portions of Teva's arguments to be "elegant" and persuasive, it also concluded that the interpretation was flawed. See Mova Pharmaceutical Corp. v. Shalala, 140 F.3d 1060, 1073 (D.C. Cir. 1998). While this portion of the Mova discussion is not crystal clear, a few months later the D.C. Circuit made clear that its Mova decision constituted a rejection of the complaint counsel's interpretation. In Purepac Pharmaceutical Co. v. Friedman, 162 F.3d 1201, 1204 (D.C. Cir. 1998), the D.C. Circuit stated: "It [the exclusivity provision of the statute] provides, as we said in Mova, that the 180-day exclusivity period for the first applicant begins running upon the occurrence of one of two events, whichever is earlier—commercial marketing by the first applicant, or a court decision in favor *of the applicant*." Id. (emphasis added).

Andrx Pharmaceuticals, Inc. v. Friedman, slip op., Civ. No. 98-0099 (D.D.C. March 30, 1998) (attached as Exhibit E), is to the same effect. In January of 1998, an ANDA first filer sought to enjoin the FDA from approving subsequent generic manufacturers prior to the expiration of the first filer's exclusivity period. In what one FDA official described as "the mother of all suits that will decide whether or not we will have authority to approve subsequent applications," see F-D-C Reports: "The Pink Sheet" (February 9, 1998), reprinted at 1998 WL 8440632, the district court's opinion in Andrx rejected the FDA's successful defense requirement and the "any court" interpretation:

> The statute provides two alternative triggering dates for the running of the 180-day period: (1) the initial marketing of the prior ANDA applicant's generic drug, or (2) a court finding that the patent is not valid or not infringed. The latter alternative clearly requires the filing of a patent suit

> **against the initial generic manufacturer**. The former does not. FDA's argument that the statue [sic] does not speak to whether the 180 days should run if the first ANDA applicant is never sued, is sued and settles, or is sued and loses, is not persuasive. **The statue [sic] is clear, in those circumstances, the 180-day period begins to run from the initial marketing of the drug.**

Andrx (Exhibit E) at 4 (emphasis added).

* * *

In summary, the only evidence complaint counsel can point to for the proposition that the "any court" interpretation was favored by the FDA as of January 1998 would be the single application of this doctrine in June 1997 in the context of the largest-selling drug in the history of the country to that date. That this was a result-oriented position (rather than one driven by the agency's reading of the law) is supported by the FDA's subsequent actions, including its decision not to publish this position for the guidance of the industry, its failure to adopt it as an official policy, and its statements to the D.C. Circuit in the Mova appeal. All suggested strongly that the FDA did not intend to again pursue the "any court" interpretation.

The courts, furthermore, had signaled that the "any court" interpretation would face problems. Complaint counsel can point only to the Fourth Circuit's Granutec decision in support of the validity of the "any court" interpretation. See Granutec, Inc. v. Shalala, 1998 WL 153410 (4th Cir. 1998), cited in Response at 4 n.4. We note that this opinion was issued two months *after* the January tentative AHP/Schering agreement that complaint counsel maintain to be the pertinent date, and that three other courts came to the opposite conclusion (i.e., that the "any court" interpretation was not valid) at about the same time. In this column were the Mova courts (both district and appellate), the Andrx court, and the Purepac court.

In fact, by the end of 1998, lawyers specializing in Hatch-Waxman patent challenges were of the view that the FDA either could not or would not adopt the "any court" interpretation of the statute. In an article appearing in the New York Law Journal in February 1999, a noted litigator summarized the prevailing view in these terms:

> Furthermore, in accordance with Mova, the Purepac court reiterated that the exclusivity period will not begin to run until the first filer who is entitled to it either commercially markets the drug or successfully concludes the patent litigation. . . .
>
> . . .
>
> . . . The current state of affairs with regard to the FDA's inability to approve the application of successive ANDA filers has raised concerns about potential collusion between the first ANDA filer and the Innovator. If the first ANDA filer never begins marketing its product and enters into a settlement with the Innovator so that it does not successfully conclude its lawsuit, successive ANDA's cannot be approved, and a generic version of the product cannot be brought to market until after the patent expires.

Charles Guttman & Jeffrey J. Macel, Litigating Drug Approvals: Patent Owners, Generic Manufacturers Go To Court, N.Y. Law Journal, February 22, 1999, at S11 (attached as Exhibit F).

In support of its contention that the "any court" interpretation was in place by January or June of 1998, complaint counsel cannot point to a single FDA pronouncement. It was only in 1999, more than a year after the ESI settlement, that the FDA began to announce a policy in favor of the "any court" interpretation. In its Proposed New Regulations of August 1999, issued fourteen months *after* ESI's final settlement, the FDA proposed to interpret Hatch-Waxman in a manner that would allow a subsequent filer to "trigger" the 180 day exclusivity period of a first filer. See FDA Proposed Rule Regarding 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42873 (to be codified at 21 C.F.R. pt. 314.107) (proposed Aug. 6, 1999).

These proposed regulations have not been adopted, however, and the FDA recently announced that it has no plans to issue final regulations.[5]

[5] See "Inside Washington's FDA Week," May 25, 2001, at 5 (attached as Exhibit G).

Exhibit A

ORIGINAL

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
RALEIGH DIVISION

GRANUTEC, INC.	. CIVIL ACTION NO.
	. 5:97-CV-485-BR
V.	. ELIZABETH CITY, NC
	. JUNE 24, 1997
DONNA E. SHALALA,	.
MICHAEL FRIEDMAN, M.D. &	.
FOOD & DRUG ADMINISTRATION	.

TRANSCRIPT OF HEARING
BEFORE THE HONORABLE TERRENCE W. BOYLE
UNITED STATES DISTRICT JUDGE

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Proceedings recorded by stenomask, transcript produced from dictation.

(The hearing in 5:97:CV-485-BR having been called, the following proceedings were held:)

THE COURT: Hello.

RESPONSE: Good afternoon, Your Honor.

THE COURT: Mr. Green, you're back representing the Plaintiff in this case.

MR. GREEN: Yes. I have to say the view is a little different from this side of the courtroom.

THE COURT: You could be in the jury box the next time.

MR. GREEN: Perhaps.

THE COURT: And Mr. Wallace is here with you.

MR. WALLACE: Yes, Your Honor; good afternoon.

THE COURT: Who represents the Government?

MR. CUTINI: Drake Cutini from the Justice Department, and I'm with Catherine Cook from the Food & Drug Administration.

MS. COOK: Good afternoon.

THE COURT: Good afternoon. And, Mr. Spearman, you're trying to get into the case; is that right?

MR. SPEARMAN: That's right, Your Honor.

THE COURT: You and Ms. Arrowood.

MS. ARROWOOD: Yes, Your Honor.

THE COURT: Is everybody going to let them in?

MR. GREEN: We have no objection, Your Honor.

MR. CUTINI: We don't object either.

THE COURT: Are you the only ones that want to get in?

MR. SPEARMAN: I believe there are some others, Your Honor.

THE COURT: Is that right? Let me take them one at a time. You're representing Genpharm; right?

MR. SPEARMAN: We represent Genpharm, Your Honor. Our firm does and Mr. Haug is from the Curtis Morris Safford firm and also we have with us Mr. George Borden of Williams & Connolly, listed, I think, is Mr. Sokolov. We all represent Genpharm.

THE COURT: And so you're going to intervene as a Defendant in this case?

MR. SPEARMAN: That's correct; Your Honor.

THE COURT: Okay. And the Government and Granutec agree to that; so we can let them in.

MR. GREEN: That's correct, Your Honor.

MR. CUTINI: Yes, Your Honor.

THE COURT: All right. I'll enter an appropriate order letting you in.

MR. SPEARMAN: Thank you, Your Honor.

THE COURT: And who else is trying to get in?

MR. LEE: Your Honor, Steve Lee for Geneva Pharmaceuticals.

THE COURT: What's the name of your company?

MR. LEE: Geneva Pharmaceuticals.

THE COURT: Geneva.

MR. LEE: We move to intervene as a Plaintiff. We're represented here by Noel Allen of Allen and Pinnix.

THE COURT: Hello, Mr. Allen.

MR. ALLEN: Good afternoon.

MR. LEE: And we've also filed a Motion for A Preliminary Injunction as an Intervenor.

THE COURT: Does anybody object to them getting in?

MR. GREEN: No, Your Honor.

MR. CUTINI: No, we don't.

THE COURT: How about you, Mr. Spearman?

MR. SPEARMAN: We have no objection to Geneva's intervention, Your Honor.

THE COURT: So you're going to come in as a Plaintiff?

MR. LEE: That's correct, Your Honor.

THE COURT: All right. They will be allowed to intervene.

And who else in coming in?

MR. STUART: Your Honor, my name is Michael Stuart. I'm with the firm of Cohen, Pontani, Lieberman & Pavane in New York. We represent Boehringer Ingelheim

Corporation, Connecticut; and this is Bob Raymond, in-house counsel for Boehringer Ingelheim. We just learned about the case last night. And we don't know if we're going to want to intervene or not. We don't have any of the papers yet. We're here just to see what's going on.

THE COURT: All right. Anybody else want to get in?

(No response.)

THE COURT: Mr. Green, you filed the case; right?

MR. GREEN: Yes, Your Honor.

THE COURT: Let me ask you some questions then to try to walk my way through it, not that that's going to work, but I'll try it anyway.

As I read some of the papers, you have settled your case with Glaxo and for whatever terms -- based on whatever terms you had with them, you've gotten a license to make ranitidine Form 1 July 10th; is that right?

MR. GREEN: That is correct.

THE COURT: And you also have the right under that agreement to start manufacturing it 45 days earlier than July 10 in order to address that market.

MR. GREEN: That is correct.

THE COURT: And in order to execute and perform under that license, does the Food and Drug Administration have to approve the manufacture and also the sale by

Granutec?

MR. GREEN: As a matter of fact, Your Honor, the way the situation stands currently, because of the status of the plant here in Wilson, North Carolina, the manufacture of the product is actually occurring in Canada, and the FDA does not --

THE COURT: Because it's not in America.

MR. GREEN: It's not in the United States; that's correct.

THE COURT: So right now, as between yourself and Glaxo, you're entitled to manufacture the drug, and you're doing that in Canada.

MR. GREEN: That's correct.

THE COURT: And you don't need FDA approval because you're not in the United States. But at some point when you bring the drug in and/or attempt to market it in the United States, you'll need FDA approval?

MR. GREEN: That is correct. In fact, Novopharm has been refused entry of the manufactured product that exists currently, because there is no FDA approval; and there is no imminent approval at this time.

THE COURT: And the reason that the FDA won't approve you has to do with this presence or absence of priority marketing, or does it have something to do with the way in which you are manufacturing the drug?

MR. GREEN: No. It has nothing to do with the application before the agency, other than the exclusivity. In other words, all other issues within the agency have been satisfied, and the sole question is whether this 180-day exclusivity is a bar then to the sale and manufacture.

THE COURT: Well, this is probably getting me off the point, so tell me if I'm wrong, but if you have a license to do it, doesn't the patent prohibition -- isn't that irrelevant? If the patent holder licenses someone to do something that's within the protection of the patent, then that's legal authority to do it. And what would exclusivity have to do with that at all?

MR. GREEN: The FDA's position is that if there is an exclusivity, 180-day exclusivity period, that that is something that is not capable of being licensed by the patentee. It's a right in a third party that would exist.

THE COURT: Well, educate me. If a year ago Glaxo wanted to license anyone to manufacture and/or sell their drug for valuable consideration, wouldn't they have the right to do that? Don't they own the exclusive right to manufacture and sell the drug?

MR. GREEN: They have the right to do that subject to the FDA regulations.

THE COURT: But that doesn't have anything to do with market competition. That has to do with the quality

of the product, doesn't it?

MR. GREEN: Well, unfortunately, perhaps because of the Hatch-Waxman Act, as you know there's this intertwining, if you will, between patent law and FDA regulations, and this one period -- 180-day period of exclusivity stands on its own. It is a right to exclude which if it is -- in fact is vested in a party, it actually allows that party to prevent competition during that 180-day period.

THE COURT: Well, they can't enforce it against the patent holder, can they?

MR. GREEN: No. It relates only to an Abbreviated Drug Application as opposed to a New Drug Application. And if you go back to the time that Zantac was originally approved in the United States, that was an application filed by Glaxo as a New Drug Application or a NDA. This 180-day exclusivity period attaches only to the ANDA procedure.

THE COURT: I know, but my point is this; and maybe I'm not making it. Suppose Glaxo decided for reasons known to them that they didn't want to manufacture ranitidine, but they still wanted to market ranitidine, and they wanted to license someone to manufacture and market ranitidine. And they did this far in advance or independent of anybody's ANDA. Could they not -- do they

not have the authority to do that?

MR. GREEN: If it's derived from their own NDA or New Drug Application, I believe there would be a methodology for that to happen. But all of the defendants in various litigations now derive their own independent approval from the agency through Abbreviated Drug Applications. So although Glaxo could have been in a position to license under its New Drug Application, that is not where -- the position of the defendants at this point.

THE COURT: So when you got a license beginning July 10th, if that's when it begins, you didn't get a license to operate under Glaxo's New Drug Application, you got permission from Glaxo to market under your ANDA; is that what you're telling me?

MR. GREEN: That's right. The license, in fact, was a patent license that allowed us to manufacture a product that would otherwise have been an infringement of their first Form 1 patent, which is expiring in July. So the license is really simply a patent license.

THE COURT: Okay.

MR. GREEN: Consequently, the right to manufacture and sell the product as a drug in the United States must derive from the ANDA that Novopharm or Granutec, in this case, filed.

THE COURT: Okay.

MR. GREEN: It's a very convoluted situation, and if this gives Your Honor any solace, the FDA has struggled with this question for about the last three months before issuing the letter on June 17th.

THE COURT: Well, I'm not trying to drag them down to my level. That wouldn't give me any comfort at all.

All right. So that's where you are. And the reason that you say the FDA isn't giving you ANDA approval is because they have interpreted the regulations to now mean that someone else has the exclusivity --

MR. GREEN: That is correct.

THE COURT: -- upon the expiration of the patent. The patent is going to expire July 25th?

MR. GREEN: Yes.

THE COURT: And that's when that exclusivity, they say, would come into effect?

MR. GREEN: The date of the 180-day exclusivity period, when it commences, actually is an issue of great debate.

THE COURT: But what do they say right now? Why is it that they won't allow you to have an ANDA approved?

MR. GREEN: They say that Genpharm was the first to file an ANDA that challenged Glaxo's Form 2 patent, and that was the first in the chain of many applications that

were filed. And that form Paragraph IV that was filed in that ANDA, as this Court knows, ultimately resulted in a settlement agreement with Genpharm. And Genpharm agreed in accordance with that original certification that the patents were valid and they would not manufacture a Form 2 product for market in the United States during the term of that patent.

Yet, nevertheless, the agency now, because of a decision that came out of the District Court of D.C. --

THE COURT: And that decision -- the merits of that decision were not appealed, were they?

MR. GREEN: There is an appeal. As far as I know, there is no brief filed in the appeal, but there is an appeal.

THE COURT: I see.

MR. GREEN: In fact, that was on a preliminary injunction motion. There is a summary judgment motion, at least according to the last information I have, that is still pending in District Court. And, in fact, the Government in that summary judgment motion is arguing that the District Court decision in that Mova decision, in fact, is wrong. Yet, nevertheless, they are applying what they view as the law coming from that Mova decision in our case. And, contrary to their regulations. And our first argument, Your Honor is that the regulations in place are

really quite clear. The regulations say that the 180-day period of exclusivity can only attach if there is an ANDA applicant that filed a Paragraph IV Certification who was first, who was sued, and who has prevailed. And the regulation is absolutely clear on that point. And their comments when they promulgated that regulation --

THE COURT: And you prevailed in the 1995 suit.

MR. GREEN: We did. And Genpharm, in that first certification --

THE COURT: Did not prevail.

MR. GREEN: Did not prevail. There was a consent judgment in that case.

THE COURT: And so your position is that no one has -- no one is entitled to the exclusivity.

MR. GREEN: That's correct. Because the first ANDA applicant was Genpharm; there is no dispute about that. But rather than prevailing as a result of that Paragraph IV Certification, they lost.

THE COURT: As you did in the 1993 case.

MR. GREEN: That's correct. The difference being in the Genpharm situation there was a settlement agreement, but it ended in a consent judgment which ordered Genpharm not to infringe the patent and in which Genpharm conceded the validity of the patent. So the net result is the same.

THE COURT: And no one else has the status of

litigating and prevailing?

MR. GREEN: At this time no one -- well, I should say, Boehringer Ingelheim, the party who has not yet intervened, actually has a judgment by the Court of Appeals for the Federal Circuit from earlier this month that basically is a coattails judgment based upon Your Honor's judgment in the District Court, and the court in their case actually following your decision entered a judgment in their favor; and there was an appellate court decision in the Boehringer Ingelheim case only a few weeks ago.

THE COURT: But that has to do with being a non-infringing ANDA, not --

MR. GREEN: That's correct. The Boehringer Ingelheim Certification, in fact, is quite far down the chain from the Genpharm filing, the Novopharm filing, the Granutec filing, the Geneva filing. Boehringer Ingelheim follows after that.

So the fact they prevailed really has no -- there is no argument here that Boehringer Ingelheim has any exclusivity right attached to it. The only argument by the Food and Drug Administration here is that Genpharm has this exclusivity that attaches to it if you apply the argument from the Mova court, which we say is wrong, because their own regulations, which have not been revoked; they were subject to rule making and comment, are still in place.

The Moya court commented those regulations, in its opinion, perhaps were not correct, but the order entered was specific to that case. That case has nothing to do with ranitidine. So, in essence, what the FDA has done in this case is to make the Moya determination rise to the level of an ultimate determination by the Supreme Court and has applied it in our case when the regulations are clearly to the contrary. And we say, as a first position, if you are applying the regulation there is really no dispute; there is no exclusivity on anyone.

THE COURT: And of course everybody for years now has been operating under a set of rules that anticipated that the first one to prevail would have exclusivity and, failing in that, there wouldn't be any exclusivity. That was the point of defending these cases, wasn't it?

MR. GREEN: Certainly when Novopharm pursued its litigation here in 1996, it was with the interpretation of the regulation that Genpharm was the only party that could have been first; it was the first; it did not prevail, and there was no exclusivity.

THE COURT: And so the intervening case that you talk about came as a windfall, didn't it? All of a sudden, without any expectation, the FDA has advanced Genpharm ahead of Novopharm where that was not expected.

MR. GREEN: It certainly was not expected that

any entity, including Genpharm, have exclusivity; that's correct Your Honor. And clearly, I think the Government will concede, that if you applied the regulations, the regulations say so.

THE COURT: And as I remember reading the newspaper, which is all I know about it, didn't Genpharm get a bunch of money from Glaxo in order to cave in in that suit?

MR. GREEN: Yes. There is an undisclosed settlement --

THE COURT: So now they've taken Glaxo's money and also -- and not paid for the right to go first and got the right to go first under the FDA's current application.

MR. GREEN: They have the right of exclusivity. What's really confusing here, Your Honor, is what does exclusivity really mean. Because Genpharm, in fact, has a new lawsuit on Form 1 that is based on --

THE COURT: That Glaxo is prosecuting against them, isn't it?

MR. GREEN: That's right.

THE COURT: In New Jersey?

MR. GREEN: It's in New York, southern New York.

THE COURT: In New York.

MR. GREEN: Right. It's far from over. In fact, they did not even give notice to Glaxo about their --

THE COURT: So even if they had exclusivity, they couldn't go to bat with it because they would be running into the potential violation of that court.

MR. GREEN: Exactly, Your Honor, and that's the irony of the situation here. If you say Genpharm has exclusivity yet because of the litigation they cannot market, so the net effect of this interpretation --

THE COURT: Glaxo gets another 180 days out of it after you've paid for a fifteen day leg up on the market.

MR. GREEN: Glaxo is certainly the winner in that situation, Your Honor. I think you can see the irony of this.

THE COURT: What's motivating the FDA in this? What kind of ax do they have to grind?

MR. GREEN: It's our understanding the agency is concerned that the Mova decision at the District Court level apply to these facts, that they are bound by Mova; and they refuse to go by the regulations.

THE COURT: Well, that's just a district judge in another district. District judges don't pay much attention to each other. That's pretty well known.

MR. GREEN: And I think it's quite clear -- and there are cases cited in our brief -- that often times an agency regulation may be found in one district or even in one circuit to not be appropriate for whatever reason, and

the agency continues to enforce it in other circuits and ultimately, as we know, that's why we have a Supreme Court. If it gets to that point, it can be resolved at the Supreme Court level. This isn't even a Second Circuit decision; this is a District Court judgment, and Mr. Cutini here, in fact, has argued the Mova case. He has argued strongly in front of that court that that judgment is wrong. We have summary judgment papers here that Mr. Cutini filed, as a matter of fact, which I would be pleased to hand up to the Court, if you would like, Your Honor, that clearly shows the Government is taking strong issue with the Mova determination. So it's really, in my mind, quite ironic that while they're arguing to the Mova court that these are wrong, he's telling Novopharm and Granutec that they must follow Mova; and they are going to tell you today that they feel constrained to follow the Mova decision when they are telling the Mova court that the Mova judgment is wrong.

THE COURT: And what's the operative event in the Mova case; is there an injunction?

MR. GREEN: There was a preliminary injunction hearing, yes. And the preliminary injunction was granted and, as I understand it, is still before the court on a summary judgment, but the preliminary injunction aspect is on appeal.

THE COURT: And that's a pharmaceutical patent

case?

MR. GREEN: Yes, it is. It deals with a product referred to as micronized glyburide, which we don't really need to go into. But the facts there are really quite different, Your Honor. There are two parties at issue, Mova and Mylan, and what happened there was Mova filed a Paragraph IV Certification. Mova was sued as a result of that certification; and they're still in litigation. In fact there was a summary judgment granted as to literal infringement, but infringement is still an issue, so they're going up. They have no trial. They is certainly no appellate court judgment, and they are off litigating. In the interim, Mylan, another pharmaceutical company, filed a Paragraph IV, and they were not sued. And then the agency continued to evaluate the Mylan ANDA and concluded that it was approvable. They looked at their regulations and said, Mova has been -- was the first; it was sued, but they haven't prevailed, and in that case we should go ahead and grant the approval to Mylan. And they did that. And Mova said, that's not fair because we were the first, we were sued, we basically haven't had our day in court here; and you shouldn't, at this point, be in a position to approve Mylan.

I think you can see that there is a drastic difference in the facts in that case where you have in

Mylan obtained approval where Mova has been sued, has not lost; they have not settled; they have not taken their bag of money and injunction and gone home.

THE COURT: Well, doesn't it almost allow the patent holder to collusively decide who gets the exclusivity?

MR. GREEN: I think that is one of the --

THE COURT: If the patent holder can pick around and decide who to sue and who not to sue, and if they have a good claim against everybody, then they get to channel the exclusivity into one direction possibly, no -- are am I missing the point?

MR. GREEN: That is absolutely the case. And if you have a situation such as Genpharm, and Genpharm has exclusivity, and there is a settlement agreement, as you've pointed out, effectively that's a mechanism for the patentee to extend the monopoly by turning the 180-day exclusivity around on its head and making it really a patent extension.

But we would say that the Mova decision, as you've pointed, Your Honor, is a District Court judgment and a judgment that even the Government does not support. So to have them deny the approval of Novopharm based on a court decision that they themselves are arguing is incorrect, to me, is unconscionable.

THE COURT: How easy is to get an injunction against the Government in a case like this?

MR. GREEN: I think Your Honor is empowered to grant an injunction based on our application.

THE COURT: To do what, enjoin them to do what?

MR. GREEN: To prevent them from applying a 180-day exclusivity bar to approval of Novopharm's ANDA. Because their finding that Genpharm has a 180-day period of exclusivity is arbitrary and capricious. It's contrary to their own regulations. These are regulations that were promulgated and have not been revoked. No activity has been taken through the rule making process to revoke those regulations. And in that situation -- I think there is a great Fourth Circuit case that we've cited in the brief that says when an agency of the Government fails to follow its own rules and regulations, its action cannot stand, and the court will strike it down.

THE COURT: What case is that?

MR. GREEN: This is Chin Zho Chai, 48 F.3d at 1340, and it's quoting United States v. Heffner, 420 F.2d 109, 811, (4th Cir. 1970) decision.

THE COURT: There is no jurisdictional problem with enjoining FDA?

MR. GREEN: The statute allows for the suit to be filed either where the FDA, the agency, is located or where

the aggrieved applicant, in this case, Granutec, is located. Granutec is a North Carolina corporation headquartered in Wilson, North Carolina. So Your Honor has jurisdiction over that issue and can enter an injunction against the FDA, as we see it.

THE COURT: Okay. Anything else you want to tell me?

MR. GREEN: That there is a second aspect of the date if Your Honor would like to hear that. It's really a separate analysis, if you will, as to when this 180-day period begins to run, which we again say is arbitrary and capricious.

THE COURT: Do you think it ran back when they settled the case a couple of years ago?

MR. GREEN: Actually it's our position -- no, because it runs from a court decision that would grant the marketing either through invalidity or through a finding of non-infringement. We actually think it was Your Honor's decision last year as a District Court determination.

See, the FDA regulations right now would say if we set everything else aside and let's assume that Granutec was the only one that filed, and Granutec brought suit -- had suit brought against it by Glaxo; there was a Paragraph IV, we prevailed in the litigation, and we should get 180-day exclusivity. If we assume that for a moment and assume

there are no other ANDAs, the question is, when does that 180-day exclusivity period begin to run. The agency says it begins to run only when the Court of Appeals finally rules upon Your Honor's decision, rather than the date that your decision is entered.

And there is a regulation that has interpreted the statute in that fashion, to say the meaning in the exclusivity statute which refers to a court decision refers to an appellate court decision. That determination by the agency, we say, is absolutely unsupported. And the reason for that is the statute says a court decision. It doesn't say a district court or an appellate court decision. The agency in 1988 -- and this is an attachment to our brief at --

THE COURT: So you think it's incumbent upon the party that prevailed, which is the appellee on appeal, to move for a stay of the running of the time. Otherwise it's running against you while the case is on appeal; is that what you're getting at?

MR. GREEN: That's exactly right.

THE COURT: You know why I know that? Because we sentence people all the time, and if you don't get a stay, you go to jail. And when you get out and win your appeal, you've already served your sentence.

MR. GREEN: Yes. It's the same kind of concept

here, Your Honor. In fact, the agency agreed with our interpretation that it should be the District Court judgment. On July 29, 1988, and this is attachment 12 to our Memorandum in Support of the Motion for Preliminary Injunction, said exactly that. It said that the court decision is the District Court decision. And if you look at the legislative history; and, again, we've referred to excerpts from the legislative history in our brief, the Reports actually referred to the District Court when referring to the time frame in which this decision would become effective.

And then what happened, when the actual regulations were promulgated for comment, the agency said, well, we're not so sure this ought to be the District Court. Maybe it's not fair to force an ANDA applicant who prevails in litigation to go to market without the comfort of that appellate court decision. We'd like some comment back. And the comment came back. And at least one comment said, gee, if I win at the District Court and I sold product, I might be liable for damages here, so I would really rather wait for the appellate court decision, and they changed their mind. In fact, the comments to the regulations say exactly that. They then said that the date for being able to market from an agency standpoint and consequently the date the 180-day period would run, would

be the appellate court decision.

But Congress didn't change the statute, and the statute can't mean one thing in 1988 and another thing in 1994 or 1997. When it used the phrase "a court decision" it had to have meant either a district court or an appellate court. The legislative history, I think, is clear in saying it meant a district court. And the agency agreed with that in 1988. Then through this rule making decided it would change that to an appellate court decision. It didn't say its interpretation was wrong -- I think this is key -- what it says, we just think it's better, it's more logical, the generic drug industry will benefit more if we interpret that as being an appellate court decision. But if Congress said when they said court decision they meant a district court decision, the legislative history said that, and the agency said that originally, they can't, through rule making, change the statute. And I think what they've done is exactly that. And if you then take a 180-day exclusivity period and you say, we don't care, Genpharm could have had the exclusivity period, Granutec could have it, Boehringer Ingelheim could have it, you still look to the court decision. And the first court decision was your decision on July 5th, 1996. You add 180 days to that, and it's long since expired. And that's our secondary position.

THE COURT: Okay.

MR. GREEN: Thank you.

THE COURT: Thank you. Mr. Cutini.

MR. CUTINI: May it please the Court, I'm Drake Cutini on behalf of the federal defendants.

Plaintiffs in this case requests an injunction ordering the FDA approve their drug product as of July 10th and not as of August 29th, which is the earliest date the FDA said it could approve.

THE COURT: Why is that?

MR. CUTINI: The reason is the 180-day exclusivity of Genpharm which began to run when the first decision finding the patent here had not infringed became final, which was in March of this year.

THE COURT: How did that become final?

MR. CUTINI: It's the Boehringer case, and they did not appeal from the aspect of the District Court decision in their favor. The district court -- this is explained in our brief -- the October 7, 1996 District Court decision in their favor became a final judgment as of January 31st of this year.

THE COURT: And that was where, in New Jersey or Connecticut?

MR. CUTINI: I believe that was Connecticut.

THE COURT: So you're saying that the 180-day

period first sprang into existence for the Boehringer -- in the Boehringer case?

MR. CUTINI: No. The 180-day -- it began because of the Boehringer case, because they were the first to prevail, but the 180 days attaches to the ANDA applicant who is the first to file and the first to file a Paragraph IV Certification. In this case, that's Genpharm.

THE COURT: You mean that the successful defense or the prevailing in the lawsuit isn't linked to the exclusivity right. That anybody just coincidentally whoever happens to file first in time always has the potential to get the exclusive right if someone fortunately down the road successfully defends; is that what you're saying?

MR. CUTINI: That is correct.

THE COURT: Well, that's -- isn't that ridiculous?

MR. CUTINI: The statute provides the 180 days can only -- is only available to the first --

THE COURT: You're saying there's an inchoate sort of 180 days sitting out there, always vested in the first to file hoping during the life of the patent that somebody will successfully prevail and then that 180 days will spring forward into the first to file. I mean, that's ridiculous. No insult intended, but, I mean, is that your

position?

MR. CUTINI: The FDA believes that is consistent with the holding in the Mova decision.

THE COURT: Well, that -- I'll never agree to that. That just doesn't make any sense at all.

MR. CUTINI: Well, in the Mova decision, as counsel for Plaintiff pointed out --

THE COURT: Think about it for a minute, though. I mean, not to be difficult with you, but think about it.

By shear chance someone files an ANDA and then any number up to infinity file other ANDAs and one during the long life of a patent happens to prevail. And on your reasoning then the first to file all of a sudden gets this right.

MR. CUTINI: The statute provides that only the first to file can get it. That's the only entity, ANDA applicant, that's entitled to it.

THE COURT: So it's meaningless then. Why would anybody else prosecute a defense if somebody else is going to get this right who hasn't done anything, who is just sitting there by the shear good fortune of being first to slip in there and get the first ANDA on the books.

MR. CUTINI: Well, the statute provides there are two things that can trigger the beginning of the 180-day period.

THE COURT: Finding the patent invalid -- no, that wouldn't --

MR. CUTINI: Yes. If a court found the patent is invalid.

THE COURT: If the patent is invalid, it is gone then.

MR. CUTINI: Correct. And another is if the first applicant begins marketing, if they prevail and begin marketing, then the 180-day period can begin at that time.

And in the Mova case the Food and Drug Administration argued that because the second applicant there -- the first applicant, Mova, was the first ANDA applicant with a Paragraph IV Certification, and they were sued. And that suit was pending at the time and, as I understand, is still pending. The second applicant, Mylan, was not sued. The Food and Drug Administration approved their product because Mova had not prevailed, but the regulation -- the Food and Drug Administration's regulation provides that in order to receive the 180 days the first applicant must prevail successfully in the patent litigation.

And the District Court there rejected that interpretation and held that all that is required is that it be a first filed ANDA with a Paragraph IV.

THE COURT: So no one other than the first to

file can ever get the 180-day period?

MR. CUTINI: That's correct. There's no dispute about that.

THE COURT: To make it simple. I mean, that's your position.

MR. CUTINI: I think that everybody would agree with that. The only ANDA applicant who can ever get 180 days is the first to file.

And the District Court in the District of Columbia in the Mova decision said that the first to file gets the 180 days whether they have prevailed or not, and it entered an injunction against the Food and Drug Administration to rescind its approval of Mylan's product. And that's the second time the Food and Drug Administration had lost that issue in the District of Columbia. The prior time was in the Inwood decision where Inwood filed an ANDA with a Paragraph IV Certification and was not sued at all. And the FDA said in that situation they were not entitled to the 180-day exclusivity because the regulation required or the interpretation, at the time, required that they be sued. The District Court rejected that interpretation and held that they were entitled to the 180 days, even though they had not been sued. And the FDA tried to appeal that decision, but it became moot, and the appeal was dismissed.

So having lost these two cases in a district

where the FDA often litigates, in this situation they decided to acquiesce in that holding.

THE COURT: What was your position before that?

MR. CUTINI: The position in the Mova case --

THE COURT: No. What was the agency's position before you were sued?

MR. CUTINI: It was that Mylan could be approved. It was the position that's stated in the regulation, which is, that in order to receive that 180 days the first intervening applicant must prevail in litigation.

THE COURT: And why did you have that position?

MR. CUTINI: That's in the regulation and it's explained in our brief here the position -- and this was in response to some comments that came in during the promulgation of these regulations. The position was that the 180-day exclusivity period should only go to a party that basically clears the way and prevails in a patent litigation.

THE COURT: Wasn't that the legislative purpose in providing the 180-day --

MR. CUTINI: I don't believe there is any explicit legislative history.

THE COURT: Well, they didn't just throw 180 days in because somebody said, let's just add 180 days. We're writing a statute now and that would be a clever thing to

do; no one will know why we did it.

MR. CUTINI: The FDA felt that it's in there to reward those who --

THE COURT: Which is why you put it in your regulations. That the first -- if the first broke ground and successfully litigated the issue, then the first would get the benefit of that labor.

MR. CUTINI: That is correct. And that's why the regulation exists and that's a -- the discussion in the Federal Register is explained in our brief.

THE COURT: And the District Judge in D.C. said, no, that's not what the law is -- what's the law?

MR. CUTINI: What the court held was that the simple act of filing first, whether that first filed ANDA Paragraph IV certifier prevails or whether it's even sued, entitles that entity to the 180 days.

THE COURT: So the logic or rationale behind that is that Congress simply threw 180 day period on there as a bonus if you were -- had a lot of forethought about filing an ANDA and got there first.

MR. CUTINI: The Court based its decision on a statute. It felt that the plain language of the statute provided, just as The Court indicated, the first one to file would receive that 180 day exclusivity.

THE COURT: For no apparent reason; just as a

bonus?

MR. CUTINI: Because it's the first to file. That's what I believe the court's reasoning to be.

THE COURT: But that's not a very strong case, is it? I mean, you're arguing against it, apparently, on appeal, aren't you?

MR. CUTINI: Well, we haven't appealed. Mylan did appeal that, the preliminary injunction; and their appeal is pending. The Food and Drug Administration didn't appeal, but filed that summary judgment motion on the merits of the case, and that motion is still pending.

THE COURT: So you're put in the awkward position here of arguing for something that you're appealing against, and if the Court rules against you here, your argument will actually be bolstered a little bit because you'll have a district court that doesn't agree with the other district court.

Or am I making that up?

MR. CUTINI: The Food and Drug Administration has, as I said, lost this issue twice in the District of Columbia.

THE COURT: So you want to be at least two for one -- two out of three now, right?

MR. CUTINI: Well, there is a potential for entities to go to different courts. And if the Food and

Drug Administration were to deny the 180-day exclusivity based on their regulation and that entity would go to the District of Columbia and claim their case was related to Mova, and they could perhaps get a ruling consistent with those decisions up there. So to ensure uniformity, what the FDA decided to do until that case is reversed on appeal, is to acquiesce in that result.

THE COURT: Well, that makes sense.

MR. CUTINI: That's why we're here. That was the reasoning for the letter issued to Plaintiff on June 17th. I think we've all read decisions where, for one reason or another, the Government did not acquiesce in a court decision, and of course they're not obligated to acquiesce in a decision, but in this case, for the reasons stated in our brief, they decided to acquiesce.

THE COURT: I'm not trying to give you a hard time; I'm just trying to figure it all out.

MR. CUTINI: And the injunction requested here is directly contrary to the Mova decision.

THE COURT: Where the judge enjoined you to do something that was contrary to your regs?

MR. CUTINI: Yes, we believe that it is contrary to our regulations; correct.

That's the first issue that deals with whether the 180 days exist. We think, based upon the reasoning of

the Mova court and consistent with that it exits and in this case belong to Genpharm.

Plaintiff's second issue is when does that begin. They say even if there is a 180-day period it began a year ago, because they were the first to prevail in District Court.

THE COURT: Well, is there some mechanism for having a stay of the running of the 180 days while the matter is on appeal.

MR. CUTINI: No. The statute provides when it begins, and it begins either when the ANDA applicant entitled to the 180 days begins marketing the product. They've obviously found a market and they've started, and their 180 days begins at that point. Or it begins with the decision of a court holding that the patent is not infringed or that it is invalid.

And Plaintiff's argument is that that begins when a district court rules in favor of the ANDA applicant. And the Food and Drug Administration stated in its regulation, and that's cited and discussed in our brief, that if that were the case, if the generic drug company or the ANDA applicant prevailed in district court and that -- and their 180 days began at that point in time, they would probably, in any case, soon lose it, because the patent holder --

THE COURT: Well, when do you say it begins?

MR. CUTINI: It begins when the decision becomes final. If it's appealed, it's when the decision of the appellate court is rendered.

THE COURT: How about if there is a cert petition?

MR. CUTINI: No. They dealt with that in the regulation. They said it is so unlikely that the Supreme Court would take cert and reverse the appellate court.

THE COURT: Well, suppose they did.

MR. CUTINI: Well, the regulation specifically says it begins with the appellate court decision. They had to make a decision, and that's what they would apply. They said the likelihood of Cert being granted and --

THE COURT: Based on the laws of probability, rather than the law.

MR. CUTINI: Well, it's based on -- on their view of, I guess, the likelihood that it would happen. And so they said if the decision is appealed, it's when the appellate court decision is rendered. If it's not appealed, it's when the district court opinion -- the right to appeal the district court opinion lapses. Because the patent holder could seek a stay. If the patent holder lost and the ANDA applicant won, and if the 180 days began at that point, but the patent holder sought a stay from the appellate court, then the generic company, the ANDA

applicant, couldn't market if there were a stay granted. And the 180 days would run.

THE COURT: Well, if the patent holder can seek a stay, why can't the applicant, the ANDA applicant, seek a stay of the running of the 180-day period.

MR. CUTINI: Well, because it's -- the time when it begins is prescribed in the statute, and they have to seek that from the Food and Drug Administration. And the Food and Drug Administration interpreted the law in this fashion so that there would not be stays but that it would -- basically it would be stayed if it were on appeal. But there is no mechanism for them to seek a stay of that 180-day period.

THE COURT: I don't see how you call it a final order if there was a case where there was a cert petition in it and they granted cert, let's say. It wouldn't be a final order then, would it?

MR. CUTINI: If that were to occur, no. But if the Food and Drug Administration --

THE COURT: What would happen to the parties in that case? It would just be tough, you know, we didn't think of that or --

MR. CUTINI: I don't think that's going to happen.

THE COURT: But suppose it does. It can happen,

is the point.

MR. CUTINI: Well, if they have the 180-day exclusivity, they could make the decision, and I don't know whether this has happened before or not, this particular scenario, but they can begin marketing and run the risk of an infringement case later on.

THE COURT: But that runs against the purpose of the 180-day exclusivity, doesn't it.

MR. CUTINI: No. They would still have the exclusivity vis-a-vis other ANDA holders. What we're talking about here is --

THE COURT: But they could be an infringer.

MR. CUTINI: With respect to the patent holder --

THE COURT: Yeah.

MR. CUTINI: -- in this limited circumstance. But I think the likelihood of it ever happening is very slim, and that's what the Food and Drug Administration believes.

THE COURT: And the reason they could still be an infringer is because they haven't prevailed; there wasn't a final order in the case. So you're saying that they could be out there marketing for 180 days at risk and then be held to be an infringer because the order wasn't final. And so you've created a 180-day period running from a final order that wasn't "a final order."

Do you follow me?

MR. CUTINI: Well, they had prevailed.

THE COURT: Well, they hadn't prevailed if it wasn't a final order. It's not a final order if it's in front of the Supreme Court and they vacated a Court of Appeals decision.

MR. CUTINI: Well, if the Supreme Court vacated it, that's correct, but they would prevail at that point. And I think that the FDA's conclusion that the likelihood of this happening --

THE COURT: No, I don't mean vacated after the Supreme Court makes a final decision in the Supreme Court. I mean during the pendency of the case in the Supreme Court after cert is granted. Isn't the effect of the Court of Appeals decision vacated; it doesn't have force at that time?

MR. CUTINI: I'm not sure how it would work. And that would depend on what kind of orders the Supreme Court entered, I think, at that point.

THE COURT: Well, we can agree it wouldn't be a final order in the Court of Appeals, can't we?

MR. CUTINI: Yes, we could, in that limited circumstance.

But the FDA has to deal in the FDA's regulations and interpreting of the statutory provision with what's

reasonable, and they based it on their experience of what is likely to happen. These cases are often appealed and based upon their --

THE COURT: What are you going to do if this Court enters an injunction ordering you to not apply the exclusivity bar against Granutec? Go to the Court of Appeals then?

MR. CUTINI: I don't know what the Food and Drug Administration will do in that circumstance, Your Honor, I don't know.

THE COURT: Is that the mechanism, that this Court would enter an injunction saying that you can't -- saying that you can't impose the bar of exclusivity. Does that also mean that you'll approve their ANDA? Because if you won't approve their ANDA, there's no point in saying that you can't impose the bar of exclusivity. Because they wouldn't be able to market the drug. Does the Court have to do both?

MR. CUTINI: I'm not sure what the Food and Drug Administration would do if the Court's injunction were to not impose the exclusivity bar at this point in time.

But back to the point of the Court, the Food and Drug Administration interpreting the statute has to deal with what is likely to happen based on its experience. And it concluded that because these cases are often appealed

that the triggering mechanism for the 180 days would not be the district court opinion. It would be, if appealed, the final would be the appellate court decision.

THE COURT: Suppose it's not appealed.

MR. CUTINI: Then it is when the right to appeal lapses from the district court's decision. Which is what happened here with the Boehringer case. They did not appeal the October 7th ruling, Glaxo did not.

THE COURT: But that was a summary judgment, wasn't it?

MR. CUTINI: It became a final judgment on January 31st of this year.

THE COURT: And that's what wasn't appealed?

MR. CUTINI: That's correct.

That's all I have, Your Honor, unless the Court has further questions.

THE COURT: No. I appreciate your being down here; thanks.

Does anybody else want to be heard.

MR. LEE: Your Honor, may I be heard, from Geneva Pharmaceuticals.

THE COURT: Well, I'll hear from Mr. Spearman first. Let's take a five minute break.

(Off the record at 3:00 p.m. until 3:10 p.m.)

THE COURT: Mr. Spearman or Ms. Arrowood, do you

want to be heard?

MR. SPEARMAN: Thank you, Your Honor.

I would like to make just a few points, basically procedurally, if I might, and with your permission then yield just briefly to Mr. Borden, who is with me, on a couple of FDA matters that came up in connection with your earlier questions to Counsel.

THE COURT: Okay.

MR. SPEARMAN: Your Honor, there is not a dispute here but that it is our client -- we represent Genpharm -- that does have a tentative approval to market ranitidine hydrochloride, and the FDA has indicated that as the first applicant to file and hand up with a Paragraph IV Certification, the FDA has concluded that it is entitled to a period of exclusivity. Just in terms of where we are procedurally, this case was filed on June 17th, and we found out about it last Friday. And then found out on Saturday that there might be a hearing Monday -- a hearing today, Tuesday, which was confirmed on Monday. We then went ahead and filed the intervention papers, and you granted the intervention earlier. We just, to be very candid, Your Honor, have not been able to prepare and present to you everything we would like to. We have not been able to prepare and present any affidavits. We have not been able to prepare and present to you, just because

of the press of time, any legal memoranda. Obviously, this case is very important to us. We fully understand it is also very important to the other parties. Even Novopharm's moving papers indicate the magnitude or importance of it in terms of finances. It's up in the hundreds of millions of dollars.

Your Honor, we would simply request that we have a short period of time, say until Monday when we could make any kind of a supplemental filing of affidavits and also a legal memorandum opposing the request for injunctive relief. And I might just make one further comment at this point, just in terms of procedure, it occurs to me from looking at the papers, Your Honor, though Novopharm has really styled this as a Request for a Preliminary Injunction, it looks like to me that it is coming very close to seeking what would be really, ultimate and final relief by the preliminary injunction. And so I simply wanted to raise the possibility that perhaps an appropriate way to proceed here, if the Court so pleased, might be simply to permit people to file virtually immediate or by Monday any materials, including motions for summary judgment. And then we would be in a position where the Court, as it saw fit, could go ahead and try to resolve the matter of final judgment on summary judgment motions instead of on preliminary injunction motion. It seems to

me that that would very likely give everybody a full opportunity to have their say and at the same time it would end up very likely with this Court deciding this matter of a very, very grave and important magnitude in the form of final judgment instead of on a preliminary injunction motion. And so I did want to raise that possibility. In any event, procedurally, Your Honor, we would like to have at least until Monday, if we could, to be able to make any supplemental filing that we would like to. All we were able to present yesterday was really an initial proposition, and we made the points there that we do not think that Novopharm has shown the probability of success. That the two courts that have ruled on this matter have ruled that exclusivity does follow the first to file.

With respect to irrevocable injury, I would simply say that any showing that Novopharm makes of irreparable injury we essentially have the mirror image of that.

THE COURT: When did you find out that you were going to be first and given this exclusivity? You certainly didn't know it a year ago.

MR. SPEARMAN: Your Honor, we -- Genpharm received a ruling from the FDA that stated it would have the exclusivity on June 17th.

THE COURT: Of this year?

MR. SPEARMAN: Yes, Your Honor.

THE COURT: That must have come as a surprise.

MR. SPEARMAN: Well, Your Honor, candidly there are different generic companies that are pursuing the right to market ranitidine hydrochloride. Several have claimed exclusivity, and there have been a number of filings actually at the FDA on this matter. I know that Geneva, for whom I think you will hear in a few minutes, made a filing at the FDA that it was entitled to exclusivity. Genpharm did the same. Novopharm communicated with the FDA, as I understand it, indicating that they didn't think anyone was entitled to exclusivity.

And what happened was the FDA made a ruling on this on June 17th. That same day --

THE COURT: Not based on your initiative, based on their interpretation.

MR. SPEARMAN: Well, they made a ruling, Your Honor, based on their interpretation of the law. And what I'm simply setting forth for you is it is certainly the case that all of the companies that had an interest in this were making representations to the FDA, and I know that both Genpharm and Geneva filed formal Citizen's Petitions with the FDA explaining what they believed to be the rights of the various parties under the provisions of the act.

THE COURT: But when the Court of Appeals in the

Federal Circuit affirmed the District Court judgment last April or so, it was pretty well understood that either no one -- well, I guess that no one would have exclusivity.

MR. SPEARMAN: Well, Your Honor, I would simply say that that has never been Genpharm's view. The statute says that the only one who can get exclusivity is the first to file an ANDA with a Paragraph IV Certification.

THE COURT: But you hadn't been -- your company hadn't been gearing up production and getting in the block, so to speak, ready to get out there and take advantage of your market, I mean, to be honest with you.

MR. SPEARMAN: To be honest, Your Honor, it is. This is another matter which was not in the Novopharm moving papers.

THE COURT: Uh-huh.

MR. SPEARMAN: Genpharm for many, many, many months now has been gearing up and has been manufacturing Form 1 in Canada, which it wants and intends to sell in the United States. Glaxo sued Genpharm in the Southern District of New York -- this was not mentioned in the Novopharm papers either -- Glaxo sued Genpharm in the Southern District of New York making a contention, one with which you are familiar, that Genpharm generic products, so Glaxo claimed, though Genpharm said it was Form 1, that it was patent infringement because it really had Form 2 in it.

That suit is still pending, and we are still battling with Glaxo on that matter and, indeed, yesterday filed what they call in New York Federal Court a Rule 56 Notice with the -- which is essentially the precursor to a summary judgment motion. So that litigation is going on in New York. Genpharm expects to prevail in that litigation and Genpharm is very, very much -- is very much trying to and intends to market ranitidine hydrochloride in the United States.

THE COURT: And so that's an answer but not really the answer to my question. My question -- what you said, I think, is that, yes, you intended to market it when the patent expires July 25th and so you were engaged in pre-expiration production, but you didn't expect to be the only one marketing it when the patent expires July 25th. You felt like you and whoever else got ANDA approval would be marketing it.

MR. SPEARMAN: Well, Your Honor, we felt that we were entitled to exclusivity. We did not know whether the FDA would grant that, and, therefore, on behalf of Genpharm a Citizen's Petition was filed with the FDA which Mr. Gordon's firm filed, explaining to the FDA why Genpharm believed that Genpharm was entitled to exclusivity. So it was not something that came as a surprise out of the sky. Genpharm has felt it could and should get exclusivity as

well as feeling it could and should market ranitidine hydrochloride. So it was not something that just popped out of the blue. It was something Genpharm had requested and sought.

THE COURT: Well, when you settled the case in Maryland in front of Judge Kauffman, after the papers were signed and everybody shook hands and walked away, Genpharm certainly didn't believe it had an exclusivity period for 180 days.

MR. SPEARMAN: Your Honor, what that did was to settle the so-called Form 2 case.

THE COURT: Right.

MR. SPEARMAN: And Genpharm did drop challenges to the validity of the 658 and the 431 patents at that time. Just as in Novopharm's case you ruled against them on that first case, and they lost the validity matter on appeal. We settled the validity matter. But we at no time waived or gave up a right to continue to go forward to try to market ranitidine hydrochloride and, in fact, essentially what Genpharm did, Your Honor, was essentially on that point is what Novopharm did, which is then try to market Form 1 instead of trying to market Form 2.

THE COURT: How are you going to get exclusivity if you didn't prevail and no one else prevailed just because you were the first to file? I mean, where was the

second leg to give you exclusivity?

MR. SPEARMAN: Well, Your Honor, on that, that is essentially the point that was -- or one of the points that was addressed by the Federal Courts in both the so-called Inwood decision and also in the Mova decision. In other words, the statute -- the liberal reading of the statute conditions being able to get exclusivity upon being the first to file an ANDA with a Paragraph IV Certification. At various times the FDA has sometimes had regulations that had additional requirements, some of which you've inquired about in previous colloquy with Counsel, including successfully defending a patent suit. But in both of those other cases the courts have ruled, essentially, that the FDA would simply not tag on or add on other requirements, such as having successfully defended a patent suit in the trial court, successfully defended a patent suit after appeal.

THE COURT: So your position then is that the shear act of being the first to file is dispositive of it and nothing else matters.

MR. SPEARMAN: Well, the first to file with a Paragraph IV Certification. I know you raised a question about that a few moment ago with Counsel as to, you know, why that would, in effect I believe you were inquiring as to why that would make any sense. I think the

Congressional history of the act really reveals that having this potential period of exclusivity and having it available for the first to file a Paragraph IV Certification, that a principal reason behind that was simply to provide an encouragement to generic companies to pursue competition with a brand name company. And one of the first cases --

THE COURT: Well, why would they need encouragement? That's how they make their living, isn't it?

MR. SPEARMAN: Well, Your Honor, when the Hatch-Waxman Amendments or Waxman-Hatch Amendments were passed, I think, which was in 1984, there were a number of different contending legislative forces and interest groups lobbying for different things. Part of it was a battle, frankly, between the generics and the brand name companies. And essentially the Act, Your Honor, really has a number of compromises in it, which were simply ultimately agreed to by the House and Senate. I mean, there are some provisions in it that one would argue certainly favor generics. Others in it would favor brand name companies. But the idea of having the incentive of the 180-day exclusivity period potentially available -- I mean the legislative history does indicate that that was to provide incentive to generic companies. And indeed the court, and I think it

was the Inwood case, that was one where the FDA took the position that if there was a first filing of a Paragraph IV Certification but no lawsuit was filed, that that applicant was not entitled to exclusivity, and the Court disagreed and said, no, the requirement is that you be the first to file with a Paragraph IV Certification, and that was supposed to be that incentive. Whether or not -- there is not any requirement there that you are only eligible for that if, in fact, a brand name company sues you and you ultimately prevail.

Your Honor, if I might, I would like to yield for a few minutes to Mr. Borden. Just to revert to what I said, we would request that the Court give us at least until early next week when we can make complete filings. Because this is very frankly from everybody's perspective, it's a very, very important matter and you can tell from the arguments that have been put forth today. All of it is -- it's not -- you know, it's not simple and I think -- I know that we at least would very much like to have that little bit of additional time.

THE COURT: Well, the reason we're here today is because I got the papers Friday. Friday is the end of the week, and I read them. And from what I could read, it appeared to me that July 10th was a critical date. And thinking about it, I felt like it was incumbent upon me to

try to have a hearing. It wasn't the kind of thing you could decide without hearing an opportunity. It's a preliminary injunction request. And the -- I figured that whichever way the Court went, somebody would go to the Court of Appeals. And running past July 10th may be a critical date. It's been well-reported -- I know you all follow this stuff -- that Novopharm settled, without going to the Supreme Court, the Glaxo case and got a license from Glaxo to do something on July 10th. And so that wouldn't be worth very much if - and I don't know what it's worth -- but it wouldn't be worth anything if July 10th came and went.

MR. SPEARMAN: Well, Your Honor, I would not dispute in any way that it's necessary and appropriate that this matter be dealt with very promptly. What I'm simply saying to you is that our client received this ruling, the ruling of exclusivity on June 17th. The first time I knew this suit was filed was very late Friday. It was only over the weekend that I knew there was going to be a hearing, and it's a very important matter to us as it is to them. I just have to be very candid and say that because of that timing we simply have not been able to get together what we would like to be able to get together to present to you, and I don't know in what way you might be able to accommodate us, but I --

THE COURT: And Genpharm is the defendant in a patent infringement suit in the Southern District of New York?

MR. SPEARMAN: That's correct, Your Honor. Glaxo is suing Genpharm in the Southern District of New York.

THE COURT: In the face of that suit and the pendency of that litigation, is Genpharm going to start marketing ranitidine, Form 1?

MR. SPEARMAN: Genpharm intends to start marketing ranitidine hydrochloride July 25th, 1997, assuming it has FDA approval to do that. And, as I have said, on June 17th we received from the FDA tentative approval.

THE COURT: And the FDA has approved you, notwithstanding the pendency of that lawsuit. That lawsuit has nothing to do from the FDA's standpoint with approval; is that what you're telling me?

MR. SPEARMAN: Your Honor, I think on that point that is going to be or is a difference of opinion between Glaxo and Genpharm and to be -- just to tell you what the situation is, number one, we are trying to get that case disposed of, as I mentioned, on summary judgment as rapidly as possible. And if that is not --

THE COURT: But you haven't filed the motions yet, have you?

MR. SPEARMAN: We've done what one has to do under New York procedure, which is to serve the other side with what they call a Rule 56 Statement, which simply sets out our authority, what we say are the uncontested facts, that the other side has to serve that back and you have to go confer with the judge on it.

And the other piece of that is we don't believe that there is any kind of stay in effect against our approval, but, if necessary, we are going to seek any kind of relief from any such stay in the Southern District of New York.

THE COURT: Who would impose that stay; the FDA?

MR. SPEARMAN: Your Honor, let me deal with that for just a moment. Glaxo sued Genpharm for patent infringement claiming there was Form 2 in the Form 1 in New York in September of 1996. It is the position of Glaxo, as we understand it, that that started, in effect, another 30-month period running. So we understand it to be Glaxo's position that there is a so-called automatic 30-month stay in effect which would not run out until 30 months after September 1996. We do not believe that to be correct, but we are filing papers with -- we have filed papers with the New York court either asking for a ruling that such a stay is not in effect or if it deems it to be in effect to dissolve it. The Courts do have power to dissolve it.

So what I am saying to Your Honor is we are taking every step we possibly can to go to market on July 25th.

THE COURT: But if that stay remains effective or if there is such a stay and it's valid, then you would be -- notwithstanding your 180-day period of exclusivity, you'd be barred from getting into the market, wouldn't you?

MR. SPEARMAN: If we -- I would say that's correct, Your Honor. I mean, we are barred from getting onto the market until we have final FDA approval as, in fact, is everybody. And if there is a stay against such approval, until the Court dissolves a stay, then we would not be able to get that until we got a declaration dissolving the stay, in effect, from the Court.

THE COURT: And the way you get this 180 days, if you get it at all, is because the FDA says that when -- what's the name Boehringer -- when Boehringer got a district judge a District Court opinion that was final in March, that triggered the running of the 180 days, as opposed to the earlier in time District Court opinion from this Court that had to go to the Court of Appeals and get affirmed and then that didn't become effective until the Court of Appeals affirmed it. Is that what I'm understanding?

MR. SPEARMAN: That is what I understand to be

the FDA position. And if I might at this point yield to Mr. Borden because I think he has got a couple of other things to say on the FDA procedure and also which may be even more responsive to the question of exclusivity, if I could yield to him for a few minutes.

THE COURT: All right.

MR. BORDEN: Thank you, Your Honor, for hearing me today. I'm going to try to highlight a few of the points of this very complex regulatory scheme that come up in papers of various parties, and I think as Mr. Spearman indicated, some of these papers didn't come to us until ten o'clock last evening, in the case of Geneva's papers. They are very complex, and I may not be able to answer all of your questions today and certainly would like an opportunity to fully explain the situation and answer any questions you have, in writing, as best we can.

The first point I want to address is the Court's concern that if the 30-month stay is still in effect that Genpharm will not be able to go to market. As Mr. Spearman indicated, it is Genpharm's position that there is no 30-month stay and can go to market.

Geneva argues that if there is a 30-month stay which prevents Genpharm from going to market there is no irreparable harm to Genpharm. That's not true, because it's FDA's position that a generic company which has a

right to exclusivity, even if it can't use it itself, can waive it as to other parties. There are cites to the Federal Register to that effect, and also we confirmed that recently with Counsel for the FDA. That means that even if the court in New York holds that Genpharm cannot go to market on July the 25th, it can enter into an agreement with Granutec or any of the other companies who can go to market to allow them to go to market in the period that otherwise would have been the exclusivity --

THE COURT: Suppose the court doesn't rule until after August.

MR. BORDEN: Well, the option is still there for us to make such an amendment.

THE COURT: I mean, there are only a few weeks or months left on this 180 days, aren't there?

MR. BORDEN: Under FDA's interpretation it runs until August 29th.

THE COURT: And how do you know that the Court will even get to it by August 29th? They haven't gotten to it yet.

MR. BORDEN: We are making every effort to raise that in as prompt a manner and get as prompt approval from the Court in New York as we can. That's what Mr. Haug's firm --

THE COURT: So let me get this straight. The 180

days really isn't 180 days. It can't start before July 25th, is that what everybody agrees?

MR. BORDEN: No. The FDA says it starts on March 3rd.

THE COURT: Uh-huh.

MR. BORDEN: So if we go to market on July 25th, we only get part of that 180 days.

THE COURT: But yet they say it wasn't until June 17th that they told you you had this 180-day right that started in March.

MR. BORDEN: There is something strange about that.

THE COURT: This is idiocy.

MR. BORDEN: Your Honor, one of the things --

THE COURT: How could you have 180 days without knowing it and have it run against you?

MR. BORDEN: Well, we tend to agree with Your Honor about that. And one of the things that we would like to be able to brief for the Court is the question of how to calculate properly that 180-day stay. We have, we believe, a potential disagreement with the FDA about that. I think everybody --

THE COURT: So you want me to enjoin -- you're going to ask me later on to enjoin the FDA to give you 180 new days as a cross-claim because you're on the same side

of the case with them.

MR. BORDEN: Well, Your Honor, because of the press of time and our client --

THE COURT: It might be. You're not sure, but that might happen.

MR. BORDEN: Exactly.

THE COURT: Exactly.

MR. BORDEN: And one of the areas I think, as Mr. Spearman indicated, that is complex and requires some briefing and a deeper understanding of how these provisions work is the calculation of exclusivity. It has been difficult for me to understand --

THE COURT: So if all the Courts grind to a halt and are untimely in their decisions and get past August 29th, as far as the FDA is concerned, nobody would have an exclusivity right. Glaxo would have kept its patent intact without generic attack, and that would be the way it goes.

MR. BORDEN: I think that's right. That would be FDA's position.

THE COURT: Well, that's why I'm having this hearing today instead of waiting a couple of weeks to have it.

MR. BORDEN: Well, if the Court would like us to brief and put forward to Your Honor as quickly as we can, and I think it would take just a few days to do this, we

can make -- we can fully brief all these issues, including how to calculate the 180 days. It is terribly important and it's complicated. And it will be difficult for me to properly address it here today.

THE COURT: And the patent holder, no negative comment intended, because they're not in the case, and this is just an observation, they have paid some money to you and taken some money, supposedly, from Novopharm and stand to also have their patent extended now if everything sort of works out to their liking.

MR. BORDEN: Well, the fact is that because there is this option for the exclusive generic company to waive its rights and because there is great incentive for it to do that, if it itself cannot use it, we believe that there is a very high probability that there is going to be generic competition in this market in July of 1997. That's another factor we think.

THE COURT: Well, but there's not going to be generic competition without the FDA approving a generic manufacturer, which they haven't done yet, other than for your company. Right? Suppose you wanted to lateral your right off between now and August 29th, whoever caught the pass would have to get in there and get FDA approval, wouldn't they?

MR. BORDEN: There are tentative approvals that

have been issued to these other companies, but they have been delayed until August 29th because of our right. We can waive that and say you can go ahead. The FDA has sanctioned that procedure. And if we can't go forward then it is certainly in our interest to strike a deal with somebody who can.

THE COURT: But you're not going to know whether or not you can go forward until you get a ruling from some judge in New York.

MR. BORDEN: Well, if we can go forward --

THE COURT: On the application of the stay, no?

MR. BORDEN: That's right. That's right. Mr. Haug perhaps can address the steps that we're taking to --

THE COURT: You can take all the steps you want, but until the judge makes a decision, there's nothing you can do about it. Obviously it's been in progress since September, right, the case. And now all of a sudden in the last week the issue of you having this 180-day right pops into being with only, whatever, 50 days left on it or 60 days left on it.

MR. BORDEN: That's right. We're doing our best, but it's --

THE COURT: And the fact that it's got 50 or 60 days left on it is just shear coincidence. I mean, the order in the Connecticut case, if that's where it was,

could have happened in January, or it could have happened in December, in which case the time would have run by now.

MR. BORDEN: Well, Your Honor, one of the positions we --

THE COURT: So it's totally illogical, isn't it?

MR. BORDEN: Well, we'd like to have the opportunity to put that in writing. We think at least one of the positions we could develop is that the case that gives rise to the beginning of a 180-day period, that could be a case involving us when we win. And we can still win and satisfy -- even if these regulations are still valid, we can still win.

THE COURT: But suppose you don't win for six months, and the patent has expired, and everybody is in the market. You'd have 180 days of exclusivity a year after the generics have been in the market, which would be meaningless.

MR. BORDEN: No. If the -- if our period does not begin to run until six months from now, and --

THE COURT: You're going to force everybody out of the market by that.

MR. BORDEN: Well, they wouldn't get in. We would hopefully have a decision holding that that was the correct interpretation.

THE COURT: But you don't have any way of knowing

that. I mean, you might not have a decision on the merits in the Southern District for an indefinite amount of time.

MR. BORDEN: Well, it could be this Court's decision that controls, because the calculation of the 180-day period has been put in issue.

THE COURT: The attractive thing about this suit is that you've got everybody here. Not that it's an attractive place to be, but that you have everybody here, so you might be able to get a ruling that was dispositive; is that what you're trying to say?

MR. BORDEN: Well, the issue has been raised here already. Geneva and Granutec have argued about how to calculate those 180 days. And while we might prefer to have the FDA look at it first or some other mechanism, it -- we need to consult our client who is in Europe at this moment, but it is very possible he will want us to brief these issues before you in the next few days, and that is one of the things we would like to do.

Your Honor, if I could highlight one more point. It's more really a point of administrative law than a FDA law, but the question, the ultimate legal question here, of course, is whether the FDA has acted arbitrarily and capriciously following the Mova decision here. And they have enunciated their rationale for doing so, which is uniformity. And when they stated that, the Court indicated

agreement in that position. Agencies often get battered by the courts for not following court decisions.

THE COURT: I don't take issue with that. I think that it's logical to be consistent, even if you're wrong.

MR. BORDEN: Well, that's exactly the point that the cases would support; and as long as you believe that, Your Honor, I think the injunction must be denied. Because as long as you think that they've acted reasonably in following Mova even if they believe Mova is incorrect, then there is no arbitrary and capricious agency action. Therefore no likelihood of success on the merits, therefore no injunction.

THE COURT: Well, but not -- I mean, the Court isn't in the position of giving deference to clear error of law. You're not telling me it's the business of the Court to recognize clear error of law and say, well, that's your opinion, and I'll just go along with it.

MR. BORDEN: Well, Your Honor, we perhaps, unlike the FDA, we're here to tell you that Mova is correct. The issue of -- although this regulatory scheme is complex, this statute is actually quite clear in what it requires of somebody to get 180 days of exclusivity. It's true, as Mr. Spearman said, we believe that the purpose of this statute is to provide an incentive for generic companies --

THE COURT: Do you think the FDA is right or wrong on the final court action being in a U.S. Court of Appeals rather than somewhere else?

MR. BORDEN: We think they're right about that. We think that's a reasonable interpretation of the statute.

THE COURT: Haven't they dealt with some contingencies and not with others? I mean, they don't deal, they admit, with the Supreme Court. They just sort of, you know, sloth that off as well, everybody doesn't go to the Supreme Court but certainly Novopharm went to the Supreme Court the first time and probably Glaxo would have gone to the Supreme Court the second time if they hadn't make their settlement. So my experience is they all go to the Supreme Court because there's too much at stake not to.

MR. BORDEN: Well, that would give more protection to the generic firm.

THE COURT: And then you've got this triggering decision, which is a District Court decision because somebody, apparently, didn't choose to appeal. So you've got inconsistencies all over the landscape. You know, they say -- in the Novopharm 2 case it only counts because they went to the Court of Appeals, but in the Connecticut case they went to the District Court, so that's okay.

MR. BORDEN: Uh-huh. And I should inform the Court that there is disagreement about whether or not

Glaxo, in fact, appealed that District Court decision that the FDA relies on as the triggering mechanism. We believe it's clear from the court file in the Federal Circuit that they did. The Notice of Appeal said they did. Now, later on their counsel said that they didn't mean to. But that is not a formal withdrawal of the appeal, and that appeal remained pending until a later date, until June 4th.

THE COURT: So you think the running of the time should be when the appeal was disposed of in June, not in March?

MR. BORDEN: Under the FDA regulation which sets the final resolution of the appeal as the correct date, yes, it should be in June or in April, the appellate resolution of the Novopharm case if it's FDA's position -- because April is now later than March, April counts. As I've said, Your Honor, it's very complex.

Your Honor, another point that has been insinuated here is that it's clear that if these regulations are valid and in place, then there is no party that can have exclusivity. We vigorously dispute that. We believe that even under the regulations, as they existed, we would have a valid exclusivity, Genpharm would, and we sent that position forth to the FDA in our Citizen Petition. The FDA did not reach that decision because it found the regulations -- it acquiesced in the Mova decision

not to enforce those regulations, which was our primary argument.

THE COURT: Well the longer I wait to make a decision, the less valuable your asset is right now, the chosen action of selling or trading or marketing your supposed exclusivity; right?

MR. BORDEN: Well, it depends on when it begins to run. If it's running now --

THE COURT: The FDA says it's running now.

MR. BORDEN: Under the FDA's interpretation you are completely correct, Your Honor.

I wanted to point out one thing about Geneva's Petition, which I gleaned from reading it late last night, which is that they are willing to accept Mova part of the way but not all of the way. They believe -- and this is because they are not a successful defendant -- so they believe the successful defense requirement is invalid, but they do not believe that the related requirement that a party -- the FDA regulations that the party not be an adjudged infringer. They believe that regulation survived Mova, which they need for that regulation to survive Mova if they're going to -- on the side of Genpharm to try to become first in line.

Your Honor, the reasoning of Mova applies equally to those two very related regulations. The reasoning is

that the statute does not place any conditions other than being the first party with this Paragraph IV Certification, and, therefore, Geneva's position is untenable on that.

MR. LEE: Your Honor, if Genpharm is going to be talking about our position, shouldn't we tell you what it is first?

THE COURT: Do you just want to talk to him?

MR. LEE: No, Your Honor. I'd like to have an opportunity to explain Geneva's position.

THE COURT: Don't you think I'll give you that chance?

MR. LEE: I'm just suggesting it would be appropriate before he responds to it.

THE COURT: Do you want him to talk now?

MR. BORDEN: I'm just about finished, Your Honor. And, as I said, because we only received Geneva's papers very late last night, I am not in a position to say a great deal more except -- well, I'll leave it at that for now. I join with the request Mr. Spearman made to have an opportunity to try to elucidate some of these matters for the Court. Thank you.

THE COURT: All right. Mr. Lee.

MR. LEE: Your Honor, both Novopharm and, I believe, Genpharm have been before you before, you're not aware Geneva has, although if you remember back to the very

first case, both Glaxo and Novopharm handed up to you some sealed exhibits. Those sealed exhibits were deposition transcripts and exhibits of a deposition of Geneva scientists during that first litigation, which was on Form 2 and Novopharm is arguing that you couldn't even make Form 1 because if you tried and used the prior art, you made Form 2. During that litigation Glaxo and Novopharm took depositions of our people who at that time, starting back as far as 1990, had developed a process for making Form 1 and had made Form 1 in very pure quality and in large amounts. And I bring that up right now because I want you to know that Geneva is the first party here who filed an ANDA for a Form 1 product alleging that it was non-infringing. And with that beginning, --

THE COURT: When did you do that?

MR. LEE: We filed in January of 1994. I believe that Novopharm filed in April of 1994, and I believe that Genpharm's was significantly -- all the others were after that.

THE COURT: I thought Genpharm filed in February of '91.

MR. LEE: They filed -- their first ANDA was on a Form 2 product with a Paragraph IV Certification that the Form 2 patent was invalid. That followed with Novopharm's ANDA saying that the -- again, they wanted to make a Form 2

product. They admitted infringement but said that the -- basically the Form 2 patent was invalid.

Those were the first two lawsuits, the one that ended in a victory for Glaxo over Novopharm and the one that ended in a consent judgment by Genpharm. We were the third ANDA to be filed, and our lawsuit was started third and only because of the vagaries of the district court dockets in various jurisdictions and because our action was stayed to allow Glaxo to prosecute the Genpharm action and stayed during the pendency of the appeal of the Novopharm case, we haven't gone to trial yet.

THE COURT: Where is your case?

MR. LEE: Our case is in New Jersey.

THE COURT: We're fast down here in North Carolina.

MR. LEE: And we've been on a pretty slow track. What I'd like to say, Your Honor, is we agree with the FDA and with Genpharm that the Mova decision -- that the FDA was within its discretion to follow the Mova decision in this Court. And, in fact, I can go into the reasons why we believe the Mova decision is a valid decision, but I would like to go to our main point, which is -- which addresses your comments that you thought it was ridiculous there was an inchoate 180-day period which always vests in the one that's first to file. And the fact is there is no such

inchoate 180-day exclusivity period. It doesn't vest necessarily with the one who is the first to file, and the FDA has promulgated regulations which address this very fact. If you look on page 6 of our brief, you'll see the regulation in point, 314.94(a)12, which provides that if you have an ANDA application with a Paragraph IV Certification which is later adjudicated invalid in litigation that that is then -- the FDA says you, ANDA applicant, must file a Paragraph III Certification, and we will treat that application as though a Paragraph IV Certification was never filed. And in the comments they say, this means that the subsequent ANDA applicant can get a 180-day exclusivity. Now that's exactly what happened in the case of Genpharm. That's exactly what happened in the case of Novopharm. They were both adjudicated infringers; they both were required by the FDA to file a Paragraph III Certifications; they both lost their place in line. And you're right, that inchoate 180-day exclusivity did not attach to them. It came down to Geneva, third in line with the first to file a Form 1 Paragraph IV Certification. We're the ones who are the first to file an ANDA containing a Paragraph IV Certification; we're the ones who are entitled to exclusivity.

THE COURT: And when does that begin to run?

MR. LEE: We have followed the FDA's

calculations. That is the long-standing regulation of the FDA in saying it follows from the Court of Appeals, the final decision of the Court of Appeals, but we argue that, in fact, the Court of Appeals decision which should be followed is the Court of Appeals decision which upheld your ruling, the Court of Appeals decision on April 4th, 1997, and therefore the period does not end until October of 1997 -- October 1st of 1997.

Now, as far as Genpharm's statement before that we are -- we are upholding part of the Mova decision and not upholding regulations which are affected by the Mova decision in the fact -- in another part, that's not accurate, Your Honor. The only regulation that Mova held was invalid was actually one section of one regulation, 314.107. That regulation implements 355(j)(4), which is the regulation which governs the approval of the Mova decision. The regulation 314.94(a)(12) that I spoke about before was adopted and implemented in 355(j)(2), which is a separate section of the statute. By the way, these implementation is fully set forth in the comments that go along with the regulations. It was adopted to implement a different statute, different section of the statute; and the fact is that there is no reason why this Court cannot approve of the -- go along with the Mova decision and at the same time follow 314.94(a)(12).

That is basically what I wanted to say, Your Honor. If you've got questions for Geneva, I'd be pleased to take them.

THE COURT: I might. Let me think for a second. Thank you; you can have a seat.

Let me ask you this, Mr. Lee. It looks to me like you could spread it out this way. Genpharm has the first in time filing in February of '91, but that was then a Form 2 ANDA, which they did not prevail on, which was later converted into a Form 1 by the filing of the Paragraph III.

MR. LEE: Into a Paragraph IV Certification covering a different product, a Form 1 product.

THE COURT: Right. Okay. And so they're earliest in time but not earliest in time with a pure Form 1 application.

MR. LEE: That's correct.

THE COURT: And they haven't prevailed.

MR. LEE: That's correct.

THE COURT: Now, Novopharm has the second Form 2 later converted into Form 1 application, so they're later in time in chronological filing, but they also have prevailed. So they prevailed, but they're neither first with a Form 1 filing nor first with a converted Form 1 filing.

MR. LEE: Well, actually, Your Honor it's a little more complicated that that. Novopharm filed the first ANDA on Form 2. The FDA doesn't allow a single generic company to file two separate ANDAs on the same NDA and, therefore, Granutec was the one who filed the Form 1 ANDA. There are two separate ANDAs, and there are two separate clocks that the FDA has ticking here. And we believe that --

THE COURT: Wait a minute. You can finish up on that.

Novopharm had to split its ANDAs between Granutec and Novopharm, and one took Form 2 and the other took Form 1.

MR. LEE: That's what we believe, Your Honor.

THE COURT: And how did that happen? Which took what?

MR. LEE: I believe that Novopharm had the Form 2 ANDA.

THE COURT: Which was April of '91.

MR. LEE: Yes.

THE COURT: And what did Granutec have?

MR. LEE: Granutec had the second ANDA, which was filed in April of 1994 following Geneva's ANDA on Form 1 in January of '94.

THE COURT: So Granutec has the second Form 1,

pure Form 1 ANDA.

MR. LEE: That is correct, Your Honor.

THE COURT: And Novopharm has the hybrid, converted Form 2, Paragraph III, Form 1 of April of '91.

MR. LEE: I lost it there.

THE COURT: Well, the reason Genpharm is here is because they had a Form 2 application that they then lost but converted under Paragraph III to a Form 1, is that not right?

MR. LEE: I may not understand the FDA's reasoning, and I don't think that they've ever set it forth here. I think that the FDA, basically, has taken the position so far that Genpharm is the first to file any ANDA containing a Paragraph IV. They have then nonapplied 314.94(a) and they have simply taken the, I guess, the explanation that that first Paragraph IV, even though it was later adjudicated to be invalid, that that is the one that gives Genpharm now the right to exclusivity, even though they lost it.

THE COURT: Well, no, it matters as to whether it's Form 2 or Form 1 --

MR. LEE: It certainly does.

THE COURT: -- because the Courts have held that these are separate patents. I mean, if we're going to just mix them together, then we're back to square one here. So

they're separate patents; they're separate drugs, and --

MR. LEE: I think the FDA should speak to that, but I think that if the FDA is relying on that 1991 Paragraph IV Certification, then that is clearly wrong, because that one was adjudicated invalid. And if they're relying on the second Paragraph IV Certification, that follows ours. And that follows Novopharm's too. Either way it's wrong, Your Honor.

THE COURT: Well, I mean, is this a point that needs to be cleared up or not?

MR. LEE: I don't think it needs to be cleared up, Your Honor, because under our analysis of the case, 314.94(a)(12) says we are the first in line.

THE COURT: Well, it might need to be cleared up under my analysis in the case, okay?

MR. LEE: Obviously, Your Honor.

THE COURT: Yeah. Mr. Spearman, do you know the answer to that?

MR. SPEARMAN: I will just speak very briefly on one point, which may be of some help.

Though there were separate Glaxo patents, as you are quite well aware, pertaining to one covering Form 1 and Form 2 and one just Form 2, it is my understanding and our understanding that the FDA has always regarded Form 1 and Form 2 ranitidine hydrochloride as being, for FDA purposes,

the same drug. And Genpharm did not file, Your Honor, a new or a separate ANDA. And nothing about Genpharm's ANDA was ever held invalid. What happened was that Genpharm simply requested to proceed with a Form 1 product instead of a Form 2 product, and the FDA indicated that that was totally appropriate, that it could be done by minor amendment and indeed that it would not be appropriate to file a new or different ANDA for Form 1 as opposed to Form 2 because the FDA considered them the same. That is my understanding. And certainly the FDA counsel might have more light to shed on that, but that is the way we are proceeding.

THE COURT: So you've never filed a Form 1 application?

MR. SPEARMAN: No, Your Honor. Genpharm, Your Honor, has only filed one ANDA on this drug -- on ranitidine hydrochloride ever, and it's the one to which you referred; it was filed in February of 1991.

THE COURT: And the thing that you were going to make then was Form 2?

MR. SPEARMAN: That's correct. We were going to make Form 2 but then later we requested to amend to make Form 1.

THE COURT: When did you do that?

MR. SPEARMAN: That was earlyish in 1996. I

don't have the exact date, Your Honor. That may have been March. The date would be in some of the papers. I believe it was March.

THE COURT: And you're treating that as a relation back to February of 1991?

MR. SPEARMAN: Well, Your Honor, we're not really treating it as a relation back. I mean, it was an amendment to the ANDA, so it wasn't a new ANDA, and the FDA told us it shouldn't be a new ANDA.

THE COURT: But yet they're accepting Form 1 ANDAs from some perspective manufacturers, aren't they? They're making or accepting distinctions between Form 1 and Form 2.

MR. SPEARMAN: Your Honor, as I understand it, and, again, the FDA counsel may certainly wish to speak to this, the FDA regards ranitidine hydrochloride Form 1 or Form 2, for drug purposes, as the same drug, even though there are different pertinent patents.

THE COURT: But the law now considers them to be separate drugs for patent purposes.

MR. SPEARMAN: That's correct, for patent purposes, Your Honor, but not for drug purposes.

THE COURT: I mean, they wouldn't accept and they couldn't authorize an ANDA for Form 2 because it would violate a patent that's going to be in existence until

2002.

MR. SPEARMAN: For patent purposes the drugs are different; for regulatory purposes I am informed that the FDA is regarding Form 1 and Form 2 as being the same drug.

THE COURT: Well, they wouldn't -- the reason that in '91 your client and Novopharm were filing ANDAs that described Form 2 was because you wanted to challenge, you wanted to infringe and challenge the existence of Form 2, the patentability of Form 2.

MR. SPEARMAN: That's correct, Your Honor, both Novopharm and Genpharm were challenging, at that point in time, the validity of the Form 2 patent.

THE COURT: And the reason that the current applicants are not filing Form 2 applications is because they want to be approved, and they know they won't be approved if they file Form 2 applications. They're not challenging, any longer, the patentability of Form 2, because that issue has been resolved.

MR. SPEARMAN: Well, Your Honor, I certainly understand that Geneva is seeking to make a Form 1 product. All I would say to that is I know there are a number of pieces of litigation between Glaxo and generic companies, including the ones here. It may very well be. I rather think it's probably the case that in some of those a generic company is, in fact, challenging the validity of

the Form 2 patent. Certainly Genpharm is not, certainly Geneva is not and, obviously, Novopharm and Glaxo --

THE COURT: Well, they would have to do it in such a way that it circumvented collateral estoppel as that may be a bar to the issues that have already been litigated.

MR. SPEARMAN: It would be a problem, obviously, if someone were not parties to the suit, and I'm simply informing the Court

THE COURT: But parties --

MR. SPEARMAN: I have seen pleadings in which other generic companies are asserting that patent is invalid. That's all I'm saying.

THE COURT: But being a party wouldn't matter. Collateral estoppel would bar nonparties as long as those issues were in the case.

MR. SPEARMAN: I don't believe it would, Your Honor.

THE COURT: Sure it would.

MR. SPEARMAN: The fact that there was a finding of validity and that that was upheld by the Federal Circuit, it might well be by way of stare decisis that that would persuade a court that it should uphold the patent. But I don't think as a technical matter it would be collateral estoppel unless whoever they were trying to

estop had been a party to the first suit.

THE COURT: That would be res judicata. It would be collateral estoppel as to the issues that were litigated. Certainly best method and double patenting. I mean, there may be some fraud on the patent office. Those things are all bound by collateral estoppel.

MR. SPEARMAN: If any of those issues had been decided against Glaxo in the first round of litigation, Glaxo would have been collaterally estopped in subsequent litigation, but, Your Honor, I don't believe it to be the case that an entity that wasn't a party to the suit would be estopped unless that new party was somehow in privity with or under the control -- or was controlling the party that wasn't an entity to the first suit.

THE COURT: Uh-huh.

MR. SPEARMAN: I think that to be the case.

THE COURT: I don't agree. All right.

Let me ask the FDA, why haven't you made a -- why haven't you discriminated between Form 1 and Form 2 applicants? It seems to me you're leaving yourself wide open here.

MR. CUTINI: My understanding is, Your Honor, they regard this as one drug.

THE COURT: But it's not one drug. If it was one drug, then the patent should have been invalid, the second

patent.

MR. CUTINI: My understanding is -- and I'm not intimately familiar with this issue -- but I think they regard it as one drug because it works in the body -- they work in the body the same way. And this is for FDA purposes.

THE COURT: Yeah, but you couldn't go to the FDA right now and ask to make Form 2 ranitidine and get approval to do it, because there's a patent bar to it. And they're agreeing with that. In fact, that would be an act of infringement.

MS. COOK: Good afternoon, Your Honor.

THE COURT: Yes, ma'am.

MS. COOK: If I might, the issue is that the FDA does not have expertise in the area of patent law, and the FDA was never given the task of determining these issues as to whether or not a patent is infringed. That is why the statutory scheme is such that when someone has filed an ANDA with FDA it is required to cite specific patents. These are identified already in the Orange Book, a list of approved drugs and any patents claimed. So that anyone who is seeking approval of an ANDA from FDA is required to cite those and give notice to the patent holders. FDA then will not decide the ANDA until the patent issues are decided outside of FDA in a courtroom such as this. So that FDA

doesn't look at a patent and determine whether or not it is infringed. Instead it is left to -- we've heard the District of New Jersey, the District of Connecticut.

THE COURT: But you wouldn't approve the application during the pendency of that challenge.

MS. COOK: That is correct, Your Honor, we cannot approve it. The statutory scheme is such that we cannot approve it for 30 months or until a Court authorizes us to approve it. It is also set up so that if litigation is taking longer than 30 months, then our approval would also be stayed, and we would not be able to. But FDA does not, in fact, determine, yes, this would be infringed or this would not be infringed.

THE COURT: Well, clearly until March of '96, Genpharm had an application to make only Form 2, which was something that you could not approve them to do.

MS. COOK: That would be correct, Your Honor.

THE COURT: And then after March of '96 they changed their application to include Form 1, which you -- following the expiration of the patent, you are authorized to approve them to make.

So why didn't you count March of '96 as being the running date for their application since that is the first time that they could make something that you could approve.

MS. COOK: We approve applications for particular

drugs. We do not approve applications for particular ways of making drugs or particular --

THE COURT: But you see my point. I mean, I understand what you do. The point is, that until March of '96 they never had an application pending to do something that they would be permitted to do, and then after that they did have an application pending to do something that they would be permitted to do. So why not use that date.

MS. COOK: Well, Your Honor, we leave that to the outside litigation, outside of FDA. And we would simply -- in this case we would look in the Mova case --

THE COURT: But that case doesn't address this point, does it? It doesn't address when the starting date should be where earlier in time the -- in that case the applicant had an application to do something that they could do. And here the applicant doesn't. They had an application from February of '91 until March of '96 to do something that they couldn't do and they can't do now, that is make Form 2.

MS. COOK: Your Honor, when I say that we follow the Mova decision, in fact the judge did comment on the very situation here. He noted that Counsel had in their oral arguments opposing the Motion for a Preliminary Injunction, Counsel for FDA and Mylan laid out scenarios of what could happen if the statute were applied as written,

without the successful defense requirement. They argued that the statute, as written, encourages frivolous -- frivolous ANDA filings and that without the successful defense requirement the entry of generic drugs into the market could be delayed or even manipulated.

Mylan predicted that if Mova loses the UpJohn patent infringement case or if the patent litigation is not concluded at the end of the 30-month automatic stay, Mova will not dare to market its product.

So that the Court here noted that the -- an analogous situation was before it where the first to file lost. But Judge Robertson's ruling was that the operation of the statute on the facts of this case may appear to FDA to be unwise and may appear to Mylan to be an invitation for abuse, but their remedy lies with Congress and not with this Court.

THE COURT: But the difference is here in this case Genpharm didn't even have an application to do anything that they could be authorized to do until March -- '96.

MS. COOK: Well, Your Honor, I've also looked quickly at Geneva's papers, so I'm not entirely ready to respond, but my understanding is this: that Genpharm made an application under -- to make a specific drug and didn't advise FDA -- it later advised FDA that two patents would

be involved. We had knowledge that two patents would be involved and left it to the court to resolve it. The next information that came to us --

THE COURT: You understand that the two patents had to do with Form 2, don't you, that there wasn't one on Form 1 and one on Form 2?

MS. COOK: I believe their first filing -- and I'm ready to be corrected -- but I believe that their first filing was -- cited both patents to FDA.

THE COURT: But the point is that there are more than two patents, one of which, I believe, applies to Form 1, and at least -- and the two that they referenced applied to Form 2. So the fact that there were multiple patents doesn't mean that they were addressing both forms. Did you understand that?

MS. COOK: I understood your point. That wasn't my understanding.

THE COURT: Well that is the fact.

MS. COOK: Okay.

THE COURT: Is it not? When you filed your ANDA -- when Genpharm filed its ANDA in February of '93, the patents you referenced were the patents for Form 2, not the patent for Form 1.

MR. SPEARMAN: Your Honor, as I understand it, the FDA has something which they refer to as a Yellow Book

where they list the patents that apply to a drug. And for Glaxo the 431 patent and the 658 were listed, I believe. Genpharm's first certification was to certify that it believed that the 431 patent was invalid and to certify that it was seeking to market when the 658 expired, the basic patent which covers both forms.

Does that answer your question?

THE COURT: No.

MR. SPEARMAN: Well, I'm sorry.

THE COURT: I'm sorry too. Who knows what the patents are? The 431 is --

MR. SPEARMAN: Perhaps Mr. Haug could --

MR. HAUG: Your Honor, if I may --

THE COURT: Let me ask Mr. Green. I'll get a straight answer from him.

The 431 patent is the Form 2 patent, right?

MR. GREEN: That's correct, Your Honor.

THE COURT: And then what's the process patent for Form 2?

MR. GREEN: That's the 133 patent.

THE COURT: All right. And what's the other one, 658?

MR. GREEN: 658.

THE COURT: And that's only Form 1?

MR. GREEN: That's ranitidine hydrochloride.

THE COURT: The generic ranitidine hydrochloride?

MR. GREEN: Correct.

THE COURT: Which that was the first patent?

MR. GREEN: That's correct.

THE COURT: At which time Glaxo said they didn't know there was Form 2.

MR. GREEN: That's correct.

THE COURT: All right. Now, when you -- what were the two patents that were addressed in your February of '91 filing, 431 and 658 or 431 and 133?

MR. SPEARMAN: Are you speaking to me, Your Honor?

THE COURT: Yes, sir.

MR. SPEARMAN: I think none of the generic companies, certainly not Genpharm, ever certified against the 133. The 133, as I understand it --

THE COURT: Is the process patent.

MR. SPEARMAN: -- processes for making ranitidine hydrochloride so they don't list it in their Orange Book, so none of generic companies certified with respect to it.

THE COURT: You certified against 431 and 658?

MR. SPEARMAN: I believe initially, Your Honor, with respect to the 658 we simply certified when it was going to expire, which meant we were not contending that it was invalid. During the course of the litigation, I

believe, Your Honor, it was in late 1993, we made an additional certification and certified that we believed the 658 patent was invalid. That was while the first lawsuit was pending after it was transferred by you up to the District of New York.

And what Genpharm, the situation now, you were talking about whether we were applying for anything that we could do. Obviously it's Genpharm's belief that it can make Form 1 without infringing the Form 2 patent, but of course Glaxo is contending that that is something we don't have a right to do because our Form 1 does infringe the Form 2.

THE COURT: What did you do in March of '96?

MR. SPEARMAN: In the spring of 1996, Your Honor, we told the F -- we had filed -- we had filed an ANDA which has the number I think it's -- well, anyway, the ANDA that we filed in February of 1991, it is the same one that has been pending with the FDA all along. In the spring of 1996 we informed the FDA that we would like to make an amendment to that ANDA to propose that we get approval for making a Form 1 ranitidine hydrochloride product. The FDA informed us, in effect, that this would be a minor amendment to your ANDA. It's not something for which you should go file a new ANDA, that we at FDA regard Form 2 and Form 1 as being the same thing, so we did that amendment.

THE COURT: So in February of '91 you applied for an ANDA to make Form 2 and said that patent 431 was invalid and patent 658 was invalid.

MR. SPEARMAN: Well, Your Honor, when we initially filed it we said that we believed 431 was invalid, and we simply certified when the 658 would expire. In other words, we did not initially certify we believed the 658 to be invalid. We added a certification during the course of the first litigation. I believe it was in late 1993, and we then certified that we believed the 658 was also invalid.

THE COURT: But you didn't apply to make ranitidine again at that time?

MR. SPEARMAN: No, we did not, Your Honor. As I said --

THE COURT: Not until March of '96?

MR. SPEARMAN: The ANDA that's been there is the one that was filed back in '91. It's the date -- it's the spring of '96, as you just said, when we said we would like to amend this to seek approval --

THE COURT: To make Form 1.

MR. SPEARMAN: -- to make Form 1; right. And the FDA said, that's what we at the FDA call a minor amendment; and the way to do it is to make a minor amendment, not to go file another ANDA. So that's what we did.

THE COURT: All right.

MR. SPEARMAN: And we informed Glaxo of that, and Glaxo sued us in the Southern District in a suit which very generally speaking is comparable to the second one you heard in Glaxo against Novopharm where Glaxo says your Form 1 has really got Form 2 in it, and it's infringing, and that's the suit that's pending up there.

THE COURT: And, Ms. Cook, why isn't the March '96 amendment the operative date for determining that Genpharm has an ANDA pending?

MS. COOK: Your Honor, the FDA's -- the FDA had the following knowledge. It had knowledge from Glaxo that it was citing two patents in its Orange Book. It had knowledge from Genpharm that Genpharm intended to make ranitidine hydrochloride. It told FDA how it -- generally how it planned to make it from a scientific point of view and not from a patent law point of view. And then cited to FDA the specific patents that would be involved and then made the Paragraph IV Certification with respect to one patent and the Paragraph III Certification with respect to the other.

The statutory scheme is such that FDA could review an application without knowing the substance of the patents so that if you are asking FDA that question then what you would require us to do is to go beyond the

applications and into the merits of the patent claims, which we have never done and which Congress expressly left to the province of the private litigation.

THE COURT: Let me ask you this if I can indulge me and shift gears for a second. In the year 2002, Form 2, the patent 431 is doing to run out. Are you going to give a generic manufacturer the right to make that and a 180-day exclusive period beginning at whatever the time is in 2002 because they have now pending an ANDA, and, if you are, how are you going to do that?

MS. COOK: The answer is we are not.

THE COURT: Why not?

MS. COOK: An application that contains a Paragraph Certification only has precedence, priority exclusivity over other Paragraph IV certifiers. If the patent is run out, then we have Paragraph III certifiers, and there would be no question of exclusivity there. Exclusivity only applies when you have Paragraph IV Certification. When a patent expires it changes to Paragraph III Certification, and there is not exclusivity with respect to those under Paragraph III.

THE COURT: So what we're learning from this evolving process is that there is probably no difference between Form 1 and Form 2 at all and that Glaxo was plenty lucky to get the second patent, much less have it affirmed.

MS. COOK: Well, I can't speak to the merits of their patent law claim, but I can tell you that FDA in its medical and scientific expertise has determined that they function in your body in the same way and that for purposes of FDA's scientific review they are the same.

THE COURT: So there isn't going to be a generic Form 2 because it would be pointless.

MS. COOK: Pointless, perhaps. I can't make that determination. It could be that someone would want to do that at some later time for some reason, but it is clear on the basis of the record that FDA has determined that ranitidine hydrochloride Form 1 and Form 2 are interchangeable for purposes of --

THE COURT: And that's why we're all here today. Because effectively, notwithstanding the litigation in 1993 and the Form 2 litigation, it really doesn't amount to anything because when this patent runs out in July, effectively the patent on ranitidine has run out, more or less.

MS. COOK: It appears so.

THE COURT: Okay.

MR. LEE: Your Honor, if I could speak to one other point. It appears from what I've heard from Genpharm and from the FDA that Genpharm never formally told the FDA that its certification had been adjudicated to be invalid,

and therefore the FDA never had the opportunity of saying to Genpharm, oh, now you have to file a Paragraph III Certification as Rule 314.94(a)(12) requires. And there was a period, I believe, of about six months between the time that Genpharm's patent -- I'm sorry -- Genpharm's application and lawsuit where they had consented to infringement, they had been adjudicated to be infringers, six months between the time that happened and the time they filed their Form 1 minor amendment with the FDA. During that period, apparently what I'm hearing is, they never told the FDA that there had been an adjudication of infringement and therefore the FDA never had the opportunity to tell them you must file a Paragraph III because that is our regulation, and we are going to follow our regulations.

THE COURT: Well, to get back to the question I was asking you about ten minutes ago, Granutec is the only party who has successfully prosecuted a claim and is first. You're first in time on Form 1, but you haven't successfully prosecuted a case.

MR. LEE: We have not successfully prosecuted, Your Honor, and I think that in this case you should take judicial notice of the fact that the reason we haven't is because our case has been stayed pending this case, the appeal of this case and pending the Genpharm case. We have

been stayed for, I would say, maybe 16 months. I filed a Motion for Summary Judgment in New Jersey in May of 1996, and it has not yet been heard. Why? Because of these --

THE COURT: Because you're in New Jersey.

MR. LEE: I'm not saying anything bad about the judges in New Jersey. But I'm saying that different courts have different docket systems. It doesn't make sense that the right to exclusivity should depend on whether or not our suit has been completed or, through no fault of our own, that we find ourselves still in the middle of litigation.

THE COURT: Okay. Well, let me take a brief recess and we'll come back and decide some procedural matters.

(Off the record at 4:30 until 4:40 p.m.)

THE COURT: Well, from a procedural standpoint, I'm willing to give you until close of business on the 30th to respond, those who want to respond, and then I'll rule on it. If you are going to file any opposing claims, they will need to be filed. Anything else? I know everybody wants to get out of here.

MR. GREEN: Does that include Granutec as well as -- as far as supplementing the papers in response.

THE COURT: Yeah, I mean, I'll hold off on doing anything until the end of the 30th, but after that whenever

I get it done, I'll file it, and I understand the timing.

Okay. Thank you very much.

(Hearing adjourned at 4:41 p.m.)

STATE OF NORTH CAROLINA)
) C-E-R-T-I-F-I-C-A-T-I-O-N
COUNTY OF PASQUOTANK)

I certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

Sandra A. Graham, CVR June 26, 1997

My commission expires: February 1, 1999

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Exhibit B

[ORAL ARGUMENT SCHEDULED MARCH 13, 1998]

Nos. 97-5082 & 97-5111

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

MOVA PHARMACEUTICAL CORP.,

Plaintiff-Appellee,

v.

DONNA E. SHALALA, Secretary of Health and Human Services, MICHAEL FRIEDMAN, M.D., Lead Deputy Commissioner of Food and Drug Administration,

Defendants,

MYLAN PHARMACEUTICALS, INC.,

Intervenor-Defendant/Appellant, and

PHARMACIA & UPJOHN COMPANY,

Appellant.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BRIEF FOR THE FEDERAL GOVERNMENT

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

1. ***Parties and Amici below:***

Parties below: The plaintiff was Mova Pharmaceutical Corp. The defendants were Donna E. Shalala, Secretary of Health and Human Services, and Michael A. Friedman, Lead Deputy Commissioner of the Food and Drug Administration. *Intervenors*: Mylan Pharmaceuticals, Inc. Pharmacia & Upjohn Company moved to intervene but that motion was not granted.

2. ***Rulings under Review:*** The ruling under review is Judge Robertson's order granting a preliminary injunction on January 23, 1997 (found in the Joint Appendix at 167-180), and the order denying Pharmacia & Upjohn Company's motion to intervene on February 10, 1997 (found in the Joint Appendix at 182).

3. ***Related Cases:*** The instant case has not previously been before this Court or any other court. The same issue is pending before the Fourth Circuit in *Granutec, Inc. v. Shalala, et al.*, Nos. 97-1873 & 97-1874 (4th Cir.; argued October 1, 1997); and in *Geneva Pharmaceuticals Inc. v. Food and Drug Administration*, No. 97-2231 (4th Cir.). A related issue is now pending before this Court in *Torpharm, Inc. v. Donna E. Shalala, et al.* No. 97-5231 (lead case), which has been fully briefed and will be argued on January 23, 1998.

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H.R. Rep. No. 857 (Part I), 98th Cong., 2d Sess. (1984), reprinted in 1984 U.S.C.C.A.N. 2647 . . . . . 3, 4, 15, 19

GLOSSARY

Act	Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, 21 U.S.C. 355(j) (Hatch-Waxman Act)
ANDA	Abbreviated New Drug Application
APA	Administrative Procedure Act
FDA	Food and Drug Administration
FDC Act	Federal Food, Drug, and Cosmetic Act
Hatch-Waxman Act	Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, 21 U.S.C. 355(j)
Hatch-Waxman Amendments	Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, 21 U.S.C. 355(j)
Mova	Mova Pharmaceutical Corp.
Mylan	Mylan Pharmaceuticals, Inc.
NDA	New Drug Application
Orange Book	Approved Drug Products with Therapeutic Equivalence Evaluations (Published by Food and Drug Administration)
Upjohn	Pharmacia & Upjohn Company

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Nos. 97-5082 & 97-5111

MOVA PHARMACEUTICAL CORP.,

Plaintiff-Appellee,

v.

DONNA E. SHALALA, Secretary of Health and Human Services, MICHAEL FRIEDMAN, M.D., Lead Deputy Commissioner of Food and Drug Administration,

Defendants,

MYLAN PHARMACEUTICALS, INC.,

Intervenor-Defendant/Appellant,

PHARMACIA & UPJOHN COMPANY,

Appellant.

BRIEF FOR THE FEDERAL GOVERNMENT

STATEMENT OF THE ISSUE

Whether the district court erred in granting a preliminary injunction based on its rejection of a Food and Drug Administration (FDA) regulation that interpreted a statutory provision granting 180 days of market exclusivity to a generic drug manufacturer.

STATUTORY AND REGULATORY PROVISIONS INVOLVED

Pertinent provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Amendments), Pub. L. No. 98-417, 98 Stat. 1585, 21 U.S.C. 355(j), which amended the Federal Food, Drug, and Cosmetic Act (FDC Act), 21 U.S.C. 301 et

seq., and pertinent provisions of FDA's regulations are attached as Addendum A, the statutory and regulatory addendum to this brief.

STATEMENT OF JURISDICTION

The district court had jurisdiction over this action pursuant to 28 U.S.C. 1331. The district court entered an order granting a preliminary injunction on January 23, 1997. JA 167. The court denied Pharmacia & Upjohn Company's (Upjohn) motion to intervene on February 10, 1997. JA 182. Mylan Pharmaceuticals, Inc. (Mylan) filed a notice of appeal on March 21, 1997 (JA 198), and Upjohn filed a notice of appeal on April 11, 1997 (JA 7, Docket Entry No. 46). This Court's appellate jurisdiction to review the preliminary injunction is invoked pursuant to 28 U.S.C. 1292(a). (By order dated May 19, 1997, the Court granted the federal government's motion to be aligned with the appellants for purposes of briefing.)

STATEMENT OF THE CASE

1. *Nature of the Case.*

This case concerns the entry into the market of a micronized glyburide product for the treatment of diabetes. Pursuant to the Hatch-Waxman Amendments, FDA promulgated a regulation that addresses when a generic drug is entitled to 180 days of market exclusivity before other generic versions of the same drug can be approved by FDA. Under FDA's regulation, only the first applicant to file an abbreviated new drug application (ANDA) for approval of a generic drug product that (1) challenges a patent, (2) is sued for patent infringement, and (3) successfully defends that suit is

entitled to the 180 days of market exclusivity. The district court (Judge Robertson) ruled that FDA's regulation was contrary to the plain language of the statute and that the 180-day period of market exclusivity must be awarded to the first ANDA applicant that challenges a patent without regard to whether that applicant is sued for patent infringement or, if sued, whether or not that applicant succeeds in the patent infringement suit.

2. ***Statutory and Regulatory Background.***

At issue in this case are provisions of the FDC Act and its implementing regulations that apply to the approval of new and generic drug applications. These provisions were added to the FDC Act through the Hatch-Waxman Amendments of 1984. Title I of the Hatch-Waxman Amendments was intended "to make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962." H.R. Rep. No. 857 (Part I), 98th Cong., 2d Sess. at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647. Until the Hatch-Waxman Amendments, manufacturers of generic drugs first approved after 1962 generally were required to duplicate the time-consuming and expensive safety and effectiveness studies already performed on the pioneer drugs. The Hatch-Waxman Amendments permit these generic drug manufacturers to rely on FDA's prior determinations of the safety and efficacy of the pioneer drug. H.R. Rep. No. 857 (Part I), 98th Cong., 2d Sess. at 14-15 (1984), *reprinted in* 1984 U.S.C.C.A.N. at 2647-48. Title II of the Hatch-Waxman Amendments was intended to provide a new

incentive for increased expenditures for research and development of pioneer drug products by "restoration of some of the time lost on patent life while the product is awaiting pre-market approval." H.R. Rep. No. 857 (Part I), 98th Cong., 2d Sess. at 15 (1984), *reprinted in* 1984 U.S.C.C.A.N. at 2648.

a. New Drug Applications (NDAs).

Pharmaceutical companies seeking to market pioneer, or innovator, drugs must first obtain FDA approval through the filing of a new drug application (NDA). 21 U.S.C. 355(a), (b). An NDA applicant, also referred to as a sponsor, is required to submit to FDA data demonstrating the safety and effectiveness of the drug. In addition, the NDA applicant must submit information on any patent which claims the drug or a method of using such drug for which a claim of patent infringement could reasonably be asserted against an unauthorized party. 21 U.S.C. 355(b)(1), (c)(2). The patent information must include the patent number and date of expiration. *Id.* FDA is required to publish this information, and does so in a publication entitled "Approved Drug Products With Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book"). *See* 21 C.F.R. 314.53(e).

b. Abbreviated New Drug Applications (ANDAs).

A manufacturer who wishes to market a generic version of a pioneer or innovator drug may submit an abbreviated new drug application (ANDA) to FDA. 21 U.S.C. 355(a), (j). Under the ANDA procedure, 21 U.S.C. 355(j), ANDA applicants may rely upon FDA

findings of safety and effectiveness for the pioneer drug product. 21 U.S.C. 355(j)(2). The statute requires that an ANDA contain, among other data and information, a certification with respect to each patent that claims the drug or the method of the drug's use for which the ANDA applicant is seeking approval and for which patent information is required to be filed. 21 U.S.C. 355(j)(2)(A)(vii). This certification must state one of the following (*id.*):

> (I) that the required patent information relating to such patent has not been filed;
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> (II) that such patent has expired;
>
> (III) that the patent will expire on a particular date; or
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> (IV) that such patent is invalid or will not be infringed by the drug for which approval is being sought.

If a certification is made under paragraph I or II indicating that patent information pertaining to the drug or its use has not been filed with FDA or the patent has expired, approval of the ANDA may be made effective immediately. 21 U.S.C. 355(j)(4)(B)(i). A certification under paragraph III indicates that the ANDA applicant does not intend to market the drug until after the expiration date of the applicable patent, and approval of the ANDA may be made effective on such expiration date. 21 U.S.C. 355(j)(4)(B)(ii).

A certification under paragraph IV -- the paragraph at issue in this case -- requires that the ANDA applicant give notice of the filing of the ANDA to the patent owner and the NDA holder for the listed drug, which notice must include a detailed statement of the

factual and legal basis for the ANDA applicant's opinion that the patent is not valid or will not be infringed. 21 U.S.C. 355(j)(2)(B). FDA may approve an ANDA with a paragraph IV certification, and the approval may become effective immediately, despite the unexpired patent, unless an action for infringement of the patent is brought against the ANDA applicant within 45 days of the date the patent owner and NDA holder receive notice of the paragraph IV certification. 21 U.S.C. 355(j)(4)(B)(iii); 21 C.F.R. 314.107(f)(2). If a patent action is brought, approval of the ANDA will not become effective until at least 30 months from the date that the patent owner and NDA holder received notice of the paragraph IV certification, unless a final decision is reached sooner in the patent case or the court otherwise orders a longer or shorter period. 21 U.S.C. 355(j)(4)(B)(iii).

As an incentive to reward companies for being the first to challenge patents, *under certain circumstances* Hatch-Waxman provides a 180-day period of market exclusivity -- barring FDA approval of other generic applicants for a 180-day period -- to an ANDA applicant who made a paragraph IV certification. 21 U.S.C. 355(j)(4)(B)(iv). It is eligibility for that period of market exclusivity that is at issue here. This section provides:

> (iv) If the [ANDA] contains a [Paragraph IV] certification and is for a drug for which a previous application has been submitted under this subsection continuing [sic: containing] such a certification, the application shall be made effective not earlier than one hundred and eighty days after --
>
> (I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous

application, or

(II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed,

whichever is earlier.

FDA has implemented this statutory provision by providing that, in order to receive 180-day exclusivity, an ANDA applicant must (1) be the first to file a paragraph IV certification, (2) be sued, and (3) successfully defend the patent infringement suit. *See* 21 C.F.R. 314.107(c)(1), which reads as follows (emphasis added):

> (1) If an abbreviated new drug application contains a certification that a relevant patent is invalid, unenforceable, or will not be infringed and the application is for a generic copy of the same listed drug for which one or more substantially complete abbreviated new drug applications were previously submitted containing a certification that the same patent was invalid, unenforceable, or would not be infringed and the applicant submitting the ***first*** application ***has successfully defended*** against a suit for patent infringement brought within 45 days of the patent owner's receipt of notice submitted under § 314.95, approval of the subsequent abbreviated new drug application will be made effective no sooner than 180 days from whichever of the following dates is earlier:
>
> (i) The date the applicant submitting the first application first commences commercial marketing of its drug product; or
>
> (ii) The date of a decision of the court holding the relevant patent invalid, unenforceable, or not infringed.

3. ***The Facts and Proceedings Below.***

a. The generic drug at issue here is a micronized glyburide product for the treatment of diabetes. JA 172 (955 F. Supp. 128,

129). Upjohn is the NDA holder for the innovator drug (Glynase, *see, e.g.*, JA 84 ¶4) and has one patent listed in the "Orange Book" that is relevant to this litigation -- U.S. Patent No. 4,916,163 (the '163 patent), with an expiration date in the year 2007. JA 172-173 (955 F. Supp. at 129).

b. Mova Pharmaceutical Corp. (Mova) filed the first paragraph IV ANDA for micronized glyburide in December of 1994. JA 172 (955 F. Supp. at 129). It gave the required notice to Upjohn, which then filed suit against Mova for patent infringement on March 27, 1995 -- which was within 45 days of Mova's notice to Upjohn. As a result of Upjohn's suit within the 45-day period, FDA was prohibited by 21 U.S.C. 355(j)(4)(B)(iii) from approving Mova's ANDA for 30 months (with exceptions not pertinent to this case). At the time of the district court proceedings, the patent litigation was still pending. JA 173 (955 F. Supp. at 129-130).

On November 22, 1995, Mylan Pharmaceuticals Inc. (Mylan) filed a paragraph III ANDA for a micronized glyburide product, seeking approval of its ANDA on the expiration of the '163 patent in 2007. In August 1996, Mylan amended its paragraph III certification to a paragraph IV certification and gave notice to Upjohn of the new certification. JA 173 (955 F. Supp. at 129-130). Upjohn, however, did not sue Mylan within the 45-day period following notice. Accordingly, on December 19, 1996, FDA approved Mylan's product because Mylan had not been sued by Upjohn and because Mova was not at that point entitled to the 180-day period of exclusivity since

it was still in litigation with Upjohn (*i.e.*, had not "successfully defended" that litigation). JA 173-174 (955 F. Supp. at 130). (We are informed that Upjohn subsequently sued Mylan for patent infringement after the 45-day period expired.)

c. Mova filed this action on December 26, 1996, seeking a temporary restraining order and a preliminary injunction to require FDA to withdraw its approval of Mylan's ANDA. JA 9-12; 171-172 (955 F. Supp. at 129). The district court granted a preliminary injunction on January 23, 1997, requiring FDA to withdraw approval of Mylan's ANDA. JA 167, 171. *See* 955 F. Supp. 128.

The district court ruled that the statute does not contain the "successful defense" requirement found in FDA's regulation. Indeed, in the district court's view, the 180-day exclusivity period is awarded based on a single criterion: that the company be the first to file a paragraph IV ANDA. JA 176 (955 F. Supp. at 130). In the district court's view, it does not matter whether or not the first filer is sued or, if sued, whether or not it loses. In this case, therefore, the simple fact that Mova had filed the first ANDA with a paragraph IV certification in and of itself entitled Mova to the 180 days of exclusivity. JA 176 (955 F. Supp. at 130). Finding that Mova would suffer irreparable injury and that the balance of harms and the public interest favored granting a preliminary injunction, the court granted Mova's request for preliminary injunctive relief and ordered FDA to suspend its approval of Mylan's micronized glyburide product until 180 days

after Mova began marketing the product or Mova won its patent litigation. JA 178-180 (955 F. Supp. at 131-132). The court also ordered Mova to post a $10,000 bond "for the payment of such costs and damages as may be incurred or suffered by any party who is found to have been wrongfully enjoined or restrained." JA 168-169 (955 F. Supp. at 132).

Although FDA disagreed with the district court's ruling, it did not appeal this interlocutory decision and, instead, expected the district court to rule promptly on the then-pending "cross motion for summary judgment" (JA 8, Docket Entry No. 47). Mylan, however, did appeal. JA 198. In the meantime, Upjohn had moved to intervene, and the district court denied that motion on February 10, 1997. JA 182. Upjohn appealed that ruling. JA 7 (Docket Entry No. 46). On September 17, 1997, the district court denied the cross motion for summary judgment "without prejudice to renewal upon completion of appeal" (JA 8, Docket Entry No. 47).

STANDARD OF REVIEW

Although the grant of a preliminary injunction is reviewed for abuse of discretion, the district court's underlying legal conclusions are reviewed *de novo*. *See, e.g., CityFed Fin. Corp. v. Office of Thrift Supervision*, 58 F.3d 738, 746 (D.C. Cir. 1995).

SUMMARY OF ARGUMENT

1. The critical issue in this appeal is whether FDA's regulation is a reasonable interpretation of the Hatch-Waxman Amendments because the district court's preliminary injunction

hinges entirely on whether FDA's interpretation was reasonable or not. In this connection, FDA's interpretation of the statute can be set aside only if it is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. Where Congress has not directly addressed an issue or has addressed it ambiguously, a court may not impose its own construction on the statute but, rather, must determine whether the agency's position is based on a permissible interpretation of the statute. In the latter situation, courts defer to an agency's interpretation if it is reasonable.

FDA's regulation is a reasonable interpretation of the market exclusivity provision in the Hatch-Waxman Amendments. It represents a careful response to the fact that neither the Hatch-Waxman Act nor the legislative history specifically addresses the precise question at issue here. Although the statute provides a 180-day period of market exclusivity to the first generic drug applicant to challenge a patent by way of a paragraph IV ANDA, the statute does not specifically address whether the exclusivity period prohibits FDA's approval of other paragraph IV ANDA applicants that are not sued for patent infringement if the first filer is sued for patent infringement but that suit is still pending. Nor does the statute address whether the exclusivity period prohibits FDA's approval of other paragraph IV ANDAs if the first filer is sued for patent infringement and loses or if it is not sued for patent infringement at all. Thus, FDA was required to fill the gap and did so reasonably by carefully considering

alternative interpretations proposed during a complete notice-and-comment rulemaking. FDA rejected some alternatives based on its balancing of these alternatives against two overarching goals of the Hatch-Waxman legislation -- to provide notice to interested parties of the existence of NDA holders' patent claims and to ensure the prompt and orderly entry of generic drugs onto the market. FDA ultimately determined that the interpretation embodied in its regulation best served these goals.

2. As demonstrated above, FDA's regulation is a reasonable interpretation of the statute. Hence, Mova was not entitled to a preliminary injunction. In addition, Mova was not entitled to preliminary injunctive relief because it did not demonstrate that the balance of harms and the public interest were in its favor.

Mova's economic injury, which the district court characterized as irreparable, is indistinguishable from the harm to Mylan. Thus, Mova's alleged harm did not warrant the granting of preliminary injunctive relief which changed the *status quo*. Further, the public's interest in this case is in both the correct interpretation of the law and the prompt and orderly entry of generic drugs onto the market. The district court's interpretation is not only wrong, it generally produces an unwarranted delay in the entry of generic drugs onto the market and here specifically resulted in the delay of approval of an ANDA for micronized glyburide product. Hence, the public interest favored denial of the preliminary injunction.

ARGUMENT

FDA'S REGULATION EMBODYING THE "SUCCESSFUL DEFENSE" REQUIREMENT *IS* CONSISTENT WITH THE HATCH-WAXMAN AMENDMENTS AND, THEREFORE, SHOULD BE UPHELD.

A.

Introduction.

1. Although the instant appeal is from an order granting a preliminary injunction, the real issue is the interpretation of the market exclusivity provision in 21 U.S.C. 355(j)(4)(B)(iv). If FDA's regulation embodies a permissible interpretation of the statute, then the district court's preliminary injunction was improperly granted and should be reversed. *See, e.g., Thornburgh v. American College of Obstetricians & Gynecologists*, 476 U.S. 747, 755-757 (1986) (where issues of law are dispositive, court may rule on the merits of the controversy, and court is not necessarily limited to the question of whether entry of injunction was error).

2. a. FDA's interpretation can be set aside only if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law * * *." 5 U.S.C. 706(2)(A). The threshold interpretation issue is whether Congress has directly addressed the question at issue or has done so ambiguously. "If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron, U.S.A. v. Natural Resources Defense Council*, 467 U.S. 837, 842-843 (1984). If Congress has not

directly addressed the issue or has done so ambiguously, the court may not "simply impose its own construction on the statute," but rather must determine whether the agency's position is based on a permissible interpretation of the statute. *Id.*; *Arent* v. *Shalala*, 70 F.3d 610, 615 (D.C. Cir. 1995). With respect to *Chevron* "step 2" cases, an agency's interpretation will be upheld if it is "sufficiently rational to preclude a court from substituting its judgment for that of [the agency]." *Young v. Community Nutrition Institute*, 476 U.S. 974, 981 (1986) (deference to FDA). *See also Mead Johnson Pharmaceutical Group v. Bowen*, 838 F.2d 1332, 1335-36 (D.C. Cir. 1988) (upholding FDA's regulatory construction of the term "approved" in the Hatch-Waxman Amendments); and *Bristol-Myers Squibb Co. v. Shalala*, 91 F.3d 1493, 1499-1500 (D.C. Cir. 1996) (upholding FDA's regulatory construction of the "same labeling" requirement in the Hatch-Waxman Amendments).

b. FDA's interpretation here is rational and should be upheld. The Hatch-Waxman Amendments do not address whether the exclusivity period prohibits FDA's approval of subsequent paragraph IV ANDA applicants when the first filer is sued for patent infringement but that suit is still pending and the subsequent filers are not sued. Nor does the statute address whether the exclusivity period prohibits FDA's approval of other paragraph IV ANDAs if the first filer is sued for patent infringement and loses or if it is not sued for patent infringement at all. FDA's

regulation, 21 C.F.R. 314.107(c)(1), reasonably fills the gap in the statute by correctly considering two overarching goals of the Hatch-Waxman legislation -- to provide notice to interested parties of the existence of NDA holders' patent claims and to ensure the prompt and orderly entry of generic drugs onto the market. *See* H.R. Rep. No. 857 (Part I), 98th Cong., 2d Sess. at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N. at 2647. Moreover, FDA's regulation was the result of careful consideration of what effect alternative interpretations of the statute -- including the interpretation imposed by the district court -- would have upon the complex drug approval process. *See, e.g., McCarthy v. Bronson*, 500 U.S. 136, 139 (1991) (agreeing that, read in isolation, petitioner's reading was the most natural one but stating that "statutory language must always be read in its proper context"); *Pilot Life Insurance Co. v. Dedeaux*, 481 U.S. 41, 51 (1987) ("In expounding a statute, we must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy.") (internal quotation marks omitted); and *Tataranowicz v. Sullivan*, 959 F.2d 268, 276 (D.C. Cir. 1992), *cert. denied*, 506 U.S. 1048 (1993) ("In determining the meaning of the statute, we look not only to the particular statutory language, but to the design of the statute as a whole and to its object and policy."). Accordingly, this Court should uphold FDA's regulation and reverse the district court's order of January 23, 1997. *See Thornburgh v.*

American College of Obstetricians & Gynecologists, *supra*, 476 U.S. at 755-757 (1986).

B.

The Hatch-Waxman Amendments Do Not Address The Specific Question At Issue; Because FDA's Regulation Is A Reasonable Interpretation, It Should Be Upheld.

1. a. At issue in this case is the generic drug marketing exclusivity provision of the Hatch-Waxman Amendments, 21 U.S.C. 355(j)(4)(B)(iv). *See* pp. 6-7, *supra*, for text of provision. That provision plainly does not address the "precise question at issue" (*Chevron*, 467 U.S. at 843), which is how to apply the 180-day exclusivity provision when the first filer of an ANDA with a paragraph IV certification is sued but is still in litigation when a subsequent paragraph IV filer is not sued and is therefore eligible for approval.

b. FDA's interpretation is embodied in 21 C.F.R. 314.107(c)(1). *See* p. 7, *supra*, for the text. As stated earlier, at the time of the Mylan approval, FDA's regulation would not grant an award of 180 days of exclusivity to Mova ***at that time*** because, although Mova was the first paragraph IV filer, it had not yet "successfully defended" the patent infringement suit brought against it by Upjohn. The "successful defense" requirement should be upheld because it has been FDA's longstanding and consistent interpretation, *see, e.g., Smiley v. Citibank (South Dakota) N.A.*,

116 S. Ct. 1730, 1733 (1996), and because it necessarily "reconci[les] conflicting policies," *Chevron, supra*, 467 U.S. at 844 (internal quotation marks and citation omitted). *See also Granutec v. Shalala*, Nos. 97-1873 & 97-1874 (4th Cir.; argued Oct. 1, 1997). Indeed, in *Granutec*, four generic drug manufacturers presented four different interpretations of the statutory provision to the Fourth Circuit, each interpretation leading to the award of 180 days of market exclusivity to the proponent of the interpretation. FDA argued *inter alia* that its interpretation (which was supported by one of the generic drug manufacturers) should be upheld because it had been the result of carefully choosing among the conflicting policies that were cited in support of the different interpretations.

FDA's current interpretation goes back to a guidance letter issued to the pharmaceutical industry in 1988. *See* 54 Fed. Reg. 28872, 28874 (July 10, 1989) (right column) (attached as Addendum B). Subsequently, in 1989, FDA issued proposed regulations which, in pertinent part, provided that the 180-day exclusivity would only be awarded to a paragraph IV applicant if that applicant had in fact been sued for patent infringement. 54 Fed. Reg. at 28894-95. The reason for this interpretation was to avoid rewarding an applicant with 180-day exclusivity if the applicant had not in fact devoted time and "resources to litigate the scope or validity of a patent." 54 Fed. Reg. 28894-95. This proposed interpretation was

also intended to prevent such applicants from delaying competition by filing a paragraph IV certification and then, if not sued, simply deferring the first "marketing" of the product until it suited them, thereby blocking all other ANDA applicants eligible for approval. *Id.* at 28894-95.

FDA received voluminous comments on all aspects of this proposed rule and addressed them at length, accepting some and rejecting others. 59 Fed. Reg. 50338 (Oct. 3, 1994). In the final rule, FDA modified the regulation to clarify that, in order to receive 180-day exclusivity, the first applicant who submits the paragraph IV certification must not only be sued in a timely-filed patent infringement suit but also must successfully defend that suit. 21 C.F.R. 314.107(c)(1). One comment to the proposed rule had stated that granting 180-day exclusivity to an applicant who had merely been sued for patent infringement "created an incentive for frivolous claims of patent invalidity or noninfringement because it would give ANDA applicants exclusivity even if the applicant was unsuccessful in defending against the patent owner's lawsuit." 59 Fed. Reg. at 50353 (comment 76) (middle and right columns). FDA agreed with this comment and clarified 21 C.F.R. 314.107(c)(1) by adding that a first-filed paragraph IV applicant also had to "successfully defend a suit brought within 45 days." *Id.* at 50353 (right column). This was consistent with FDA's 1988 industry letter, and thus clarified what FDA intended all along.

c. There is no legislative history explaining the scope of

the 180-day exclusivity period. As a result, FDA's regulation focused on a balancing of two overarching goals of the Hatch-Waxman legislation -- (1) to provide notice to interested parties of the existence of NDA holders' patent claims and (2) to ensure the prompt and orderly entry of generic drugs onto the market to compete with high cost innovator drugs, *see* H.R. Rep. No. 857 (Part I), 98th Cong., 2d Sess. at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N. at 2647 -- against the effect that alternative interpretations of the statute (offered by both pioneer and generic drug manufacturers) would have upon these goals. *See* 59 Fed. Reg. 50338 (Oct. 3, 1994). How the 180-day exclusivity provision is interpreted can have a profound effect on the entry into the market of generic drug products.

For example, the district court decision awards 180 days of market exclusivity simply and solely because an ANDA applicant was the first to file an ANDA with a paragraph IV certification. JA 176 (955 F. Supp. at 130). This is so even if the applicant loses the patent litigation. However, when the applicant loses the patent litigation, there can be no trigger for exclusivity under 21 U.S.C. 355(j)(4)(B)(iv)(II) because there is no court decision declaring the patent invalid or not infringed. The sole trigger for exclusivity, therefore, is the date of first commercial marketing under 21 U.S.C. 355(j)(4)(B)(iv)(I), and the earliest date for commercial marketing in the scenario where the first paragraph IV filer loses the patent infringement suit is the

expiration of the patent. (In this case, the patent expires on April 10, 2007. *See, e.g.*, JA 58 ¶5.) Consequently, under the district court's interpretation, if the applicant who is entitled to exclusivity begins commercial marketing immediately upon the expiration of the patent, the earliest other paragraph IV ANDAs could be approved would be 180 days after the patent expires. This result clearly removes the incentive other generic companies have in pursuing the paragraph IV route and challenging a patent. Even if they were to succeed in their patent infringement suits (for example, because they litigated better or had a different product that did not infringe the patent), they could not market their product ahead of the first filer.

Furthermore, focusing again on the scenario where the first filer loses its patent infringement suit, there is no requirement that the first filer begin marketing on the expiration date of the patent. It could, instead, indefinitely delay its first commercial marketing which, in turn, would indefinitely delay FDA's approval of other paragraph IV ANDAs.[1]

Finally, the district court's interpretation has the same adverse consequences where the first paragraph IV applicant is not sued. The district court's interpretation grants the applicant 180

1/ Whether any other ANDA would be approvable at the time the patent expires would depend on whether any ANDA had originally been submitted containing a paragraph III certification, which seeks approval on the expiration date of the patent. FDA regulations prohibit paragraph IV ANDAs from being amended to paragraph III ANDAs and thus circumventing the first applicant's exclusivity. *See* 21 C.F.R. 314.94(a)(12)(viii).

days of exclusivity in this situation as well. However, because there has been no patent infringement suit, the only trigger for exclusivity is, again, the first commercial marketing even though the applicant is eligible for immediate approval. Under this scenario, an applicant who was not sued for patent infringement could then indefinitely delay the beginning of marketing. That delay, in turn, would indefinitely delay generic competition in general. This could occur because, although the ANDA applicant has obtained approval, it is unable to bring the product to market. This could also occur because in certain circumstances it would be in the ANDA applicant's financial interest not to market the drug. This last possibility is very real because many generic drug companies are "captive" -- wholly or partly owned by innovator companies.[2] Congress clearly did not intend this result.

In contrast, under FDA's regulation, if the first filer is not sued or is sued but loses, no generic company is awarded market exclusivity. Therefore, there is no potential for delay at all, and all subsequent paragraph IV filers can be approved immediately if they are not sued for patent infringement or, if sued, can be approved either (a) on the date when a court finally determines

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2/ In *Granutec*, two of the generic drug manufacturers involved in the litigation are Genpharm Inc. and Geneva Pharmaceuticals, Inc. Genpharm Inc.'s corporate parent is Merck, and Geneva Pharmaceuticals, Inc. is owned by Novartis (which was formed by the merger of Sandoz and Ciba-Geigy). *See* Corporate Disclosure Statement of Genpharm Inc. at p. i-ii of Genpharm Inc.'s Opening Brief in *Granutec*. (The disclosure statement can be found in Addendum C to this brief.)

that the patent is invalid or not infringed or (b) at the expiration of the 30-month stay in section 355(j)(4)(B)(iii).

Moreover, under FDA's regulation, if the first filer loses the patent infringement suit, other paragraph IV ANDA applicants still have an incentive to proceed with their paragraph IV ANDAs and any resulting litigation or to try to design around the patent at issue because, if a subsequent paragraph IV applicant is successful in defending its product, it would be eligible for approval notwithstanding the first filer's defeat.

On the other hand, if the first filer eventually wins its suit, it would still be entitled to a certain measure of market benefit under FDA's regulation. It would have 180 days of market exclusivity as to later-filed paragraph IV ANDAs that were not yet approved by FDA when the first filer succeeded in the patent infringement suit and thus became entitled to exclusivity.

d. For clarification, one final point should be made. FDA's approval of Mylan's drug product in this case did not preclude Upjohn from suing Mylan for patent infringement after the 45-day notice period expired. The Hatch-Waxman Act and FDA's regulation only bar FDA from approving a paragraph IV ANDA if the innovator drug company sues the paragraph IV filer within the 45-day period. A patent infringement suit filed after the 45-day period does not have any effect on FDA's action and is solely a matter between the litigants.

C.

The Balance Of Harms And The Public Interest Compelled Denial Of A Preliminary Injunction.

As demonstrated above, FDA's regulation is a reasonable interpretation of the statute and, therefore, must be upheld. Thus, Mova was not entitled to a preliminary injunction. In addition, Mova was not entitled to preliminary relief because it did not demonstrate that the balance of harms and the public interest were in its favor. *See, e.g., WMATC v. Holiday Tours, Inc.*, 559 F.2d 841, 843 (D.C. Cir. 1977).

The district court ruled that, without a preliminary injunction ordering FDA to withdraw approval of Mylan's ANDA immediately, Mova would have suffered irreparable injury in the form of economic loss that could not have been compensated by other corrective relief. JA 178-179 (955 F. Supp. at 131). However, whatever business Mova claims it would lose by the marketing of Mylan's product is precisely the economic harm caused to Mylan from the grant of the preliminary injunction. Accordingly, because granting a preliminary injunction to Mova produced a similar injury to Mylan, Mova's injury did not warrant the granting of preliminary injunctive relief altering the *status quo* unless it was required to post a bond commensurate with the loss Mylan would suffer. *Cf. CityFed Fin. Corp. v. Office of Thrift Supervision*, *supra*, 58 F.3d at 746. Given the uncertainty of the delay caused by the district court's order, the $10,000 bond the district court required Mova to

post (*see* JA 168-169; 955 F. Supp. at 132) hardly reflects the potential loss Mylan could suffer. (Under the district court's order, the greatest delay would result from a loss by Mova in its patent infringement suit, which would bar FDA from approving Mylan's ANDA until 180 days after the expiration of the patent in on April 10, 2007.)

Finally, while it is true, as the district court noted (JA 179; 955 F. Supp. at 131), that there is a public interest in the correct interpretation of the law, there is also a public interest in the prompt and orderly entry of generic drugs onto the market. The district court's decision ignored this important consideration. In this regard, the approval of Mylan's product ahead of Mova's did not implicate any health or safety concerns. (FDA had determined that Mylan's generic product was safe and effective.) The only issue was whether the statute barred approval because of the market exclusivity provision, which is an economic issue. Significantly, the district court's decision has harmed the public interest because it created a delay in the approval of an ANDA for generic micronized glyburide (and created the potential for delay until the expiration of the patent in 2007). As a result, the public interest favored denial of the preliminary injunction.

CONCLUSION

For the foregoing reasons, the district court's order granting a preliminary injunction should be reversed.

Respectfully submitted,

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D.C. CIRCUIT RULE 28(d) CERTIFICATE

Pursuant to D.C. Circuit Rule 28(d), I hereby certify that this brief does not exceed 12,500 words.

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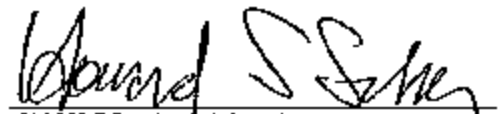

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* Public Citizen v. Department of Justice, 491 U.S. 440 (1989) . . . 5

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* Cases and authorities chiefly relied upon are marked by an asterisk.

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* 54 Fed. Reg. 28872 (July 10, 1989) 11
* 59 Fed. Reg. 50338 (Oct. 3, 1994) 9
* 62 Fed. Reg. 63268 (Nov. 28, 1997) 9-10

GLOSSARY

Act	Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, 21 U.S.C. 355(j) (Hatch-Waxman Act)
ANDA	Abbreviated New Drug Application
APA	Administrative Procedure Act
FDA	Food and Drug Administration
FDC Act	Federal Food, Drug, and Cosmetic Act
Hatch-Waxman Act	Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, 21 U.S.C. 355(j)
Hatch-Waxman Amendments	Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, 21 U.S.C. 355(j)
Mova	Mova Pharmaceutical Corp.
Mylan	Mylan Pharmaceuticals, Inc.
NDA	New Drug Application
Paragraph IV	21 U.S.C. 355(j)(2)(A)(vii)(IV)
Teva	Teva Pharmaceuticals, USA
Upjohn	Pharmacia & Upjohn Company

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Nos. 97-5082 & 97-5111

MOVA PHARMACEUTICAL CORP.,

Plaintiff-Appellee,

v.

DONNA E. SHALALA, Secretary of Health and Human Services, MICHAEL FRIEDMAN, M.D., Lead Deputy Commissioner of Food and Drug Administration,

Defendants,

MYLAN PHARMACEUTICALS, INC.,

Intervenor-Defendant/Appellant,

PHARMACIA & UPJOHN COMPANY,

Appellant.

REPLY BRIEF FOR THE FEDERAL GOVERNMENT

SUMMARY OF ARGUMENT

The issue in this case is whether the district court correctly determined that the language of 21 U.S.C. 355(j)(4)(B)(iv), which grants 180 days of market exclusivity to a generic drug manufacturer in certain circumstances, is clear and unambiguous. In finding no ambiguity, the district court rejected the interpretation of that provision embodied in a regulation of the Food and Drug Administration (FDA) and granted Mova Pharmaceutical Corp.'s request for a preliminary injunction.

1. a. Mova Pharmaceutical Corp. (Mova) argues that the Court should focus solely on the statutory provision at issue, in-

isolation from the rest of the statute, to determine its meaning. This is contrary to well-settled precedent that establishes that ambiguity must be determined in the context of the statute as a whole. In any event, the statutory provision, standing alone, is plainly ambiguous as demonstrated by the three alternative interpretations posited by the drug company parties and *amicus curiae* in this case. Mova's argument, moreover, would compel the Court to adopt an interpretation that will produce results completely at odds with the statute as a whole and its design. That is an unacceptable proposition. In this connection, it is significant that Mova never once addresses the problem of when the first paragraph IV filer loses its patent infringement suit -- which means that no generic drug can be marketed before the expiration of the patent at issue. Such an interpretation removes all incentive for other generic manufacturers to design around the patent (because it makes no difference whether they can ultimately succeed in that endeavor -- they still cannot receive FDA approval before expiration of the patent as a result of the first filer's loss). This is an absurd result and cannot be what Congress intended.

b. Mova argues that FDA's "successful defense" requirement -- which requires a lawsuit before awarding exclusivity -- is unreasonable because the idea of the exclusivity provision is to create an incentive for challenging a patent and getting generic drugs to market sooner rather than later. According to Mova, if

exclusivity is not awarded when there is no patent infringement suit against the first paragraph IV filer, there will be no incentive to pursue a paragraph IV challenge to a patent. This is not true. To be sure, Congress wanted to encourage a challenge to patents in appropriate circumstances. But a first filer is not hurt by not being sued. Although it will not be awarded market exclusivity, it will not have spent resources defending a patent infringement suit. Moreover, by being the first filer, a generic manufacturer positions itself to be awarded 180 days of market exclusivity if it is subsequently sued and succeeds in the patent infringement suit. Although there can be instances like the instant case, where the first filer loses out on the full force of exclusivity, this certainly does not undercut the reasonableness of the regulations vis-a-vis the universe of potential fact patterns. And, further, without the lawsuit requirement, if the first filer is not sued, it can -- for economic or other reasons -- indefinitely delay marketing so as to delay the entry of generics onto the market, thus undercutting the public interest in having generic drug products available.

c. Mova argues that hypothetical scenarios cannot be considered in determining whether the statute is ambiguous. FDA, however, discussed hypotheticals not solely for the purpose of demonstrating ambiguity -- which it demonstrated elsewhere in its briefing -- but to demonstrate that its interpretation is reasonable. In determining whether one interpretation or another best serves the statutory language and purpose, FDA would be

derelict in not testing potential interpretations against likely scenarios.

d. Finally, Teva Pharmaceuticals, USA, proposes an alterative interpretation that FDA has not previously addressed and is not directly presented by the facts of the instant case. Therefore, the Court need not address the validity *vel non* of this interpretation at this time but should note that, for purposes of determining whether the statute is ambiguous, this is yet another interpretation that the language of the statute permits.

2. As to the harms at issue, we argued that Mova's economic injury was no greater or different than the economic injury suffered by Mylan Pharmaceuticals, Inc. as a result of the district court's injunction. Consequently, Mova did not suffer the kind of injury that would warrant the issuance of a preliminary injunction altering the *status quo* in the absence of a bond commensurate with Mylan's potential loss. Mova does not rebut this argument.

Mova argues that the public interest is not served by FDA's interpretation because that interpretation will reduce competition in the long run. In fact, it is Mova's interpretation that is disastrous for competition. Indeed, Mova's interpretation had the potential for delaying approval of an abbreviated new drug application (ANDA) for a generic micronized glyburide product until the year 2007. FDA's interpretation, by contrast, avoids such disastrous effects altogether, by removing the possibility of delay more successfully that any other interpretation.

ARGUMENT

A. The Merits.

1. a. The crux of Mova's plain language argument is that this Court is required to focus narrowly on the language of a particular provision, in isolation from the statute as a whole. Mova Br. at 11-13. The problem with this argument is that it is contrary to well-settled authority. Indeed, in determining whether a particular statutory provision is ambiguous, courts must look beyond the narrow focus of the provision at issue and *must* consider the provision within the context of the statute as a whole. *See* Opening Br. at 14-15; *see also, e.g.*, Brown v. Gardner, 513 U.S. 115, 115 S. Ct. 552, 555 (1994) ("Ambiguity is a creature not of definitional possibilities but of statutory context."); Washington Legal Foundation v. United States Sentencing Commission, 17 F.3d 1446, 1449-1450 (D.C. Cir. 1994).

In addition, Mova's argument would compel this Court to adopt an interpretation that will produce results completely at odds with the statute as a whole and its design of bringing generic drug products to market in a prompt and orderly fashion. *See, e.g.*, Opening Br. at 18-19. In Public Citizen v. Department of Justice, 491 U.S. 440, 454 (1989), the Supreme Court noted that, in searching for statutory meaning, courts should avoid interpretations that produce an "odd result" -- one that is at odds with statutory purpose -- or "absurd results." (Internal quotation marks and citations omitted.) In this connection, it is

significant that Mova never once addresses the main problem with its interpretation: namely, that, if the first paragraph IV filer is always entitled to 180 days of market exclusivity, even when it loses its patent infringement suit, that loss means that no generic version of the pioneer drug can be marketed before the expiration of the patent at issue (plus 180 days for subsequent paragraph IV filers). *See* Opening Br. at 19-20. (In this case, the patent at issue, the '163 patent, does not expire until 2007.) This is so, significantly enough, even if subsequent paragraph IV filers *win* in their patent infringement litigation. (Subsequent filers might win because of better litigation or because they were able to design around the original patent. *See* Opening Br. at 20.) This is an absurd result and cannot be what Congress intended.

Further, once the first filer has wrapped up exclusivity and then loses its patent infringement suit, the rest of the generic field can only stand by and wait for the patent to expire. Other generic manufacturers have no incentive to try to design around the patent because it makes no difference whether they can ultimately succeed in that endeavor -- they still cannot receive FDA approval. *See* Opening Br. at 20.

b. In any event, Mova is wrong that the statutory language, standing alone, is unambiguous. The drug companies here have advanced at least three interpretations separate and distinct from FDA's. Mova's interpretation is one, and the *amicus* brief filed by Teva Pharmaceuticals, USA, provides two others: one, that the 180-

day exclusivity period can be triggered by a subsequent paragraph IV filer's victory in a declaratory judgment action (Teva Br. at 12-16) and, two, that the statutory language permits "sequentia[l]" exclusivity periods "such that each subsequent challenger's approval timing is governed by the immediately preceding ANDA" (Teva Br. at 8 n.6). These interpretations only serve to buttress FDA's argument that section 355(j)(4)(B)(iv) is ambiguous. *See also* Opening Br. at 17, citing Granutec, Inc. v. Shalala, et al., Nos. 97-1873 & 97-1874 (4th Cir.; argued Oct. 1, 1997) (drug companies advanced four different interpretations each granting exclusivity to the proponent of the interpretation).[1]

2. a. Mova argues that FDA's "successful defense" requirement -- which requires a lawsuit before awarding exclusivity -- is unreasonable because the idea of the exclusivity provision is to create an incentive for challenging a patent and getting generic drugs to market sooner rather than later. According to Mova, if exclusivity is not awarded when there is no patent infringement suit against the first paragraph IV filer, there will be no incentive to pursue a paragraph IV challenge to a patent. Mova Br. at 17-18. This is not true.

To be sure, Congress wanted to encourage a challenge to patents. But a first filer is not hurt by not being sued. Although, under FDA's regulation, it will not be awarded market

1/ Moreover, Teva adds an interpretation not included in Granutec.

exclusivity, it was not required to spend resources defending a patent infringement suit.

b. Moreover, there is no merit to Mova's contention that, without exclusivity where no lawsuit is filed, "no patent challenges would occur." Mova Br. at 19. *See also* Mova Br. at 9 (FDA's interpretation "would practically foreclose all future paragraph (IV) certifications and frustrate the intent of Congress"); and 22 ("It will reduce competition in the long run and drive prices higher * * *."). By being the first filer, a generic manufacturer positions itself to be awarded 180 days of market exclusivity if it is subsequently sued and succeeds in the patent infringement suit. This is the incentive to be the first filer, and it is significant. Although there can be situations like the instant case where the first filer loses out on the full force of exclusivity (*see* Opening Br. at 22), this certainly does not undercut the reasonableness of the regulations vis-a-vis the universe of potential fact patterns. And, further, without the lawsuit requirement, if the first filer is not sued, it can -- for economic or other reasons -- indefinitely delay marketing so as to delay the entry of *all* generic versions of its drug onto the market and thus undercut the public's interest in having generics available. *See* Opening Br. at 20-22.

c. Although FDA's interpretation is not perfect, that alone does not render it unreasonable or invalid. *See, e.g.*, Auer v. Robbins, 117 S. Ct. 905, 909 (1997) (quoting Chevron U.S.A. Inc. v.

Natural Resources Defense Council, Inc., 467 U.S. 837, 842-843 (1984)) (where Congress has not directly spoken to the precise question at issue or has done so ambiguously, the courts must sustain the agency's "approach so long as it is 'based on a permissible construction of the statute'"). The fact is that FDA's interpretation does a better job of carrying out Congress's intent of bringing low cost generics to the market in a prompt and orderly fashion than any of the alternatives proposed by the drug companies and better than that adopted by the district court. Thus, it should be upheld.

3. Mova argues that hypothetical scenarios cannot be considered in determining whether the statute is ambiguous. Mova Br. at 13-14. FDA, however, has discussed hypotheticals not solely for the purpose of demonstrating ambiguity -- which it demonstrated elsewhere in its briefing -- but to demonstrate that its interpretation is reasonable. (The hypotheticals discussed in our opening brief, at pp. 18-22, were among the scenarios FDA considered during the rulemaking period. *See, e.g.*, 59 Fed. Reg. 50338, 50353 (Oct. 3, 1994).) Moreover, in determining whether one interpretation or another best serves the statutory language and purpose, FDA would have been derelict in its duty had it failed to test the potential interpretations against likely scenarios.

4. Mova argues that FDA's interpretation "has been anything but consistent * * *." Mova Br. at 14 n.11. In support of this argument Mova cites FDA's notice at 62 Fed. Reg. 63268 (Nov. 28,

1997) in which FDA announced termination of FDA's temporary acquiescence in the district court's decision in the instant case. FDA had decided to apply the Mova district court decision to future abbreviated new drug applications (ANDAs) in an effort "to promote administrative uniformity" in the interpretation of section 355(j)(4)(B)(iv). However, the notice makes clear that FDA always believed its interpretation was correct and that its temporary acquiescence would end if it was able to obtain a reversal of Mova by this Court (62 Fed. Reg. at 63269, left column) or if the district court were to reverse field in deciding Mova's summary judgment motion then pending. (The district court, however, denied summary judgment without prejudice because of the pendency of the instant appeal. *See* Opening Br. at 10; JA 8, Docket Entry No. 47.) Significantly, because a district court decision in North Carolina disagreed with the district court here and upheld the validity of the regulation at issue here (that decision is now on appeal in the Granutec case in the Fourth Circuit), FDA determined that it had not achieved the uniformity it sought and that, as a result, it would terminate its temporary acquiescence. 62 Fed. Reg. at 63269 (left and middle columns). Therefore, Mova's statement that FDA's interpretation has not been consistent is not accurate. Further, FDA should be applauded, not condemned, for its attempt to look beyond its own litigative interests in an effort to establish at least temporary stability for the drug industry.

5. Mova cites the decision in Inwood Laboratories, Inc. v. Young, 723 F. Supp. 1523 (D.D.C.), vacated as moot, 43 F.3d 712

(D.C. Cir. 1989), in support of its interpretation. Mova Br. at 15-17. However, the district court decision there has little or no value because it was vacated after the case became moot during FDA's appeal.

6. Mova argues that there is no merit to Mylan's argument that the 180-day exclusivity provision must be interpreted as requiring the existence of a lawsuit against the first filer. Mova Br. at 14-15. A substantial portion of Mylan's argument is based on some of the statements made by FDA in its notice of proposed rulemaking. *See* Mylan Br. at 31-32, citing 54 Fed. Reg. 28872, 28894-95 (July 10, 1989). Although our opening brief did not discuss this aspect of the rulemaking, we note here that FDA has not abandoned its reliance on that reasoning. In our view, the discussion cited by Mylan provides additional support for believing that Congress viewed the 180 days of market exclusivity as a reward for litigating patent validity or applicability and, therefore, for imposing a "successful defense" requirement.

7. The *amicus curiae*, Teva, argues that the statute should be interpreted to permit the subsequent filer, if not sued for patent infringement by the NDA holder, to begin marketing 180 days after it succeeds in a declaratory judgment action declaring the patent invalid or not infringed no matter the status of the first filer's patent infringement suit. Teva Br. at 12-16. (Teva says the same should apply even when the subsequent filer is sued for patent infringement and wins before the first filer's suit is concluded.

Teva Br. at 15.) FDA has not previously addressed this interpretation and is not directly presented by the facts of the instant case. Therefore, the Court need not address the validity *vel non* of this interpretation at this time, but it should note that, for purposes of determining whether the statute is ambiguous, this is yet another interpretation that the language of the statute permits.

B. The Balance of Harms.

1. In our opening brief (at 23-24), we argued that Mova's alleged economic harm is no greater in amount than the harm to Mylan resulting from the district court's injunction. Thus, we argued, Mova did not demonstrate the kind of harm that entitled it to preliminary injunctive relief. Mova does not rebut this argument.

Moreover, preliminary injunctive relief is intended to maintain the *status quo ante* the litigation. Consarc Corp. v. U.S. Treasury Department, 71 F.3d 909, 912 (D.C. Cir. 1995) (defining "*status quo ante*" to mean "the state of affairs prior to the District Court's order at issue in the appeal"). Here, because the injunction changed, rather than maintained, the *status quo ante*, the district court erred in issuing a preliminary injunction without requiring the posting of a bond commensurate with Mylan's potential economic loss. *See* Opening Br. at 23-24.

2. Mova argues that the public interest is not served by

FDA's interpretation because that interpretation "will reduce competition in the long run" (Mova Br. at 22). As demonstrated above, it is Mova's interpretation that has the most disastrous effects on competition. Indeed, Mova's interpretation had the potential for delaying entry of a generic micronized glyburide product until the year 2007. Mova attempts to sidestep this point by citing the fact that it recently won a favorable decision in its patent infringement litigation with Pharmacia & Upjohn Company and that, as a result, the way is now cleared for the marketing of generic versions of micronized glyburide. *See* Mova Br. at 23 n.19. Clearly, this argument misses the point. The fact that events turned out well for Mova, and thus the public, does not rebut the fact that Mova's interpretation could have had disastrous results for the public. FDA's interpretation, by contrast, avoids such disastrous effects altogether by removing the possibility of delay more successfully than any other interpretation offered by the drug company parties, *amicus curiae*, or the district court.

CONCLUSION

For the foregoing reasons and the reasons stated in our opening brief, the district court's order granting a preliminary injunction should be reversed.

Respectfully submitted,

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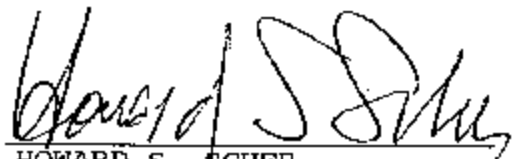

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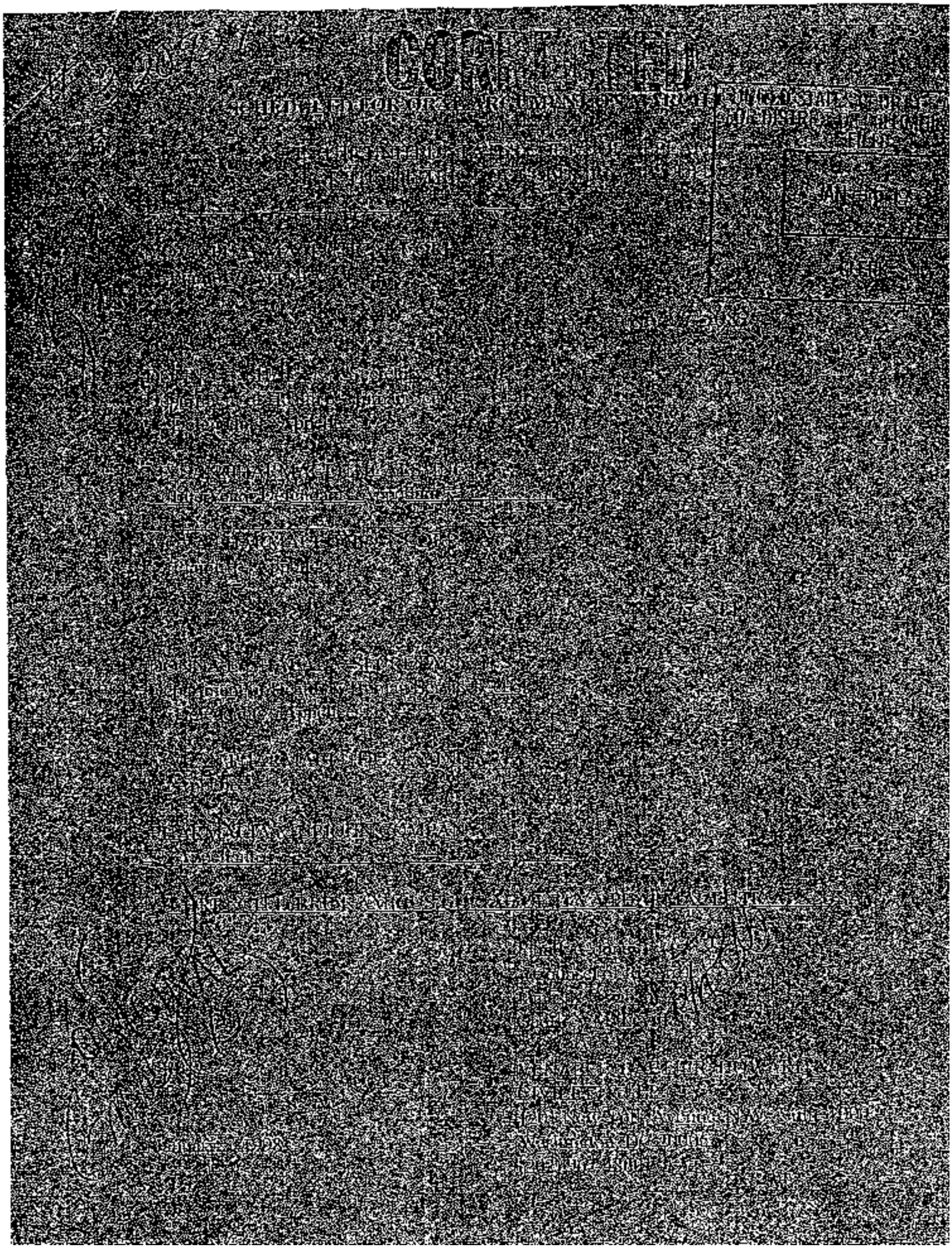
Exhibit D



CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

A. Parties and Amici

Except for Amicus Curiae Teva Pharmaceuticals USA, all parties, intervenors and amici appearing before the district court and in this Court are listed in the Briefs for the Appellant, Mylan Pharmaceuticals, Inc.

Disclosure Statement Pursuant to F.R.A.P. 26.1 and Circuit Rule 26.1.

Amicus Curiae Teva Pharmaceuticals, USA hereby identifies its following parent companies, subsidiaries, and affiliates that have issued shares or debt securities to the public: Teva Pharmaceuticals Industries Ltd.

B. Rulings Under Review

References to the rulings at issue appear in the Brief for Appellant, Mylan Pharmaceuticals, Inc.

C. Related Cases

This case has not been on review before this or any other court. On December 2, 1997, the United States District Court for the District of Puerto Rico issued a judgment for the defendant in Upjohn Co. v. Mova Pharmaceutical Corp., No. 95-CV-1378 (D.P.R., Perez-Gimenez, J.), a patent infringement case that involves the same innovator drug patent, and two of the parties, as are involved in these appeals.

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OTHER AUTHORITIES

H.R. Rep. No. 98-857, Part I (June 21 1984), reprinted at 1984 U.S. Code. Cong. Adm. News 2686 14

H.R. Rep. No. 98-857, Part II (August 1, 1994), reprinted at 1984 U.S. Code. Cong. Adm. News 2686 ..... 2, 7

REGULATIONS

21 C.F.R. § 314.107 (c)(1) 10
21 C.F.R. § 314.94(a)(12)(i)(A)(4) 13
62 Fed. Reg. 63,269 (Nov. 28, 1997) 4

* Authorities upon which we chiefly rely are marked with asterisks.

GLOSSARY:

ANDA: Abbreviated New Drug Application

NDA: New Drug Application

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

MOVA PHARMACEUTICAL CORP., Plaintiff - Appellee, v. DONNA E. SHALALA, Secretary, U.S. Department of Health & Human Services; Et al., Defendants - Appellees, MYLAN PHARMACEUTICALS, INC., Intervenor Defendant - Appellant	No. 97-5082
MOVA PHARMACEUTICAL CORP., Plaintiff - Appellee, v. DONNA E. SHALALA, SECRETARY, U.S. Department of Health & Human Services, et al., Defendants - Appellees, MYLAN PHARMACEUTICALS, INC., Appellee, PHARMACIA & UPJOHN COMPANY, Appellant.	No. 97-5111

CORRECTED BRIEF AMICUS CURIAE OF
TEVA PHARMACEUTICALS, USA

Teva Pharmaceuticals, USA ("Teva") respectfully submits this Brief, amicus curiae, seeking reversal of one aspect of the district court's preliminary injunction, in which it ordered that the Food and Drug Administration (FDA) suspend its approval of Mylan's Abbreviated New Drug Application ("ANDA") for the generic drug micronized

glyburide. Specifically, the court erroneously ordered that the statutory bar to FDA approval of Mylan's ANDA could only be terminated 180 days after a decision of non-infringement in a patent infringement case pending in the United States District Court for the District of Puerto Rico between the patent holder Pharmacia & Upjohn Company ("Upjohn") and respondent Mova Pharmaceutical Corp. ("Mova"). Teva submits that this aspect of the order below is based on an incomplete and erroneous interpretation of the controlling statutory provisions in 21 U.S.C. § 355. The defective injunction threatens to render inoperative important parts of the carefully crafted statutory scheme for approval of generic drugs.

The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. 98-417 ("Waxman-Hatch"), established a "flexible schedule of ANDA approval effectiveness dates"[1] with multiple pathways under which multiple manufacturers may obtain FDA authorization to begin marketing generic versions of established drugs prior to the expiration of the patent(s) covering such drugs.[2] Simply stated, Waxman-Hatch does not contain any automatic "exclusivity" provision for any generic drug company. What Waxman-Hatch does is put a 180-day hold on the effective date of FDA approval of

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[1] H.R. Rep. No. 98-857, Part II, 15 (August 1, 1994) reprinted at 1984 U.S. Code. Cong. Adm. News 2686, 2699 (Aug. 1, 1984).

[2] FDA, purporting to acquiesce in the lower court's injunction until such time as this Court ruled, recognized the existence of these alternative pathways in June 1997, when it determined the date for first marketing of generic versions of ranitidine (the generic name for Zantac®). FDA granted the first party to challenge the Zantac® patent the right to a 180 day delay in approval of the Abbreviated New Drug Application of subsequent challengers, but started the 180 day clock on the date one of the subsequent challengers, Boehringer Ingelheim, prevailed in a later-filed patent infringement case involving the same product and patent. See Granutec v. Shalala, 5:97-CV-485-BO(1)(D.N.C., July 7, 1997) (unpublished order) (see Attachment A). This FDA decision spawned the separate Granutec litigation involving the same statutory provision, which is currently pending before the Fourth Circuit. Granutec v. Shalala, No. 97-1874. Oral argument was heard on October 1, 1997, but as of the date of this submission, no decision had been issued.

a Paragraph IV ANDA if a previous Paragraph IV ANDA has been submitted challenging the same patent.

The running of the 180-day hold may be triggered by one of several statutorily specified events, including: (1) the previous paragraph IV applicant's first marketing of the drug; (2) a successful defense of a patent infringement action by a "previous applicant;" (3) a declaratory judgment that a subsequent applicant's ANDA does not infringe the patent; and (4) a court ruling in another patent infringement case that the patent is invalid. The district court, however, ignored two of those statutory pathways and thereby entered a mandatory injunction which ordered FDA to exercise its authority in a manner that would deny other generic drug companies their rights under these statutory alternatives, either in this case or in other cases if this order is relied upon as a precedent.

The current litigation is an important case that will have broad ramifications in determining the respective rights of innovator and generic drug companies. The decision below already has affected the outcome of other court cases and ANDA approval decisions, multiplying the confusion and uncertainty within both the FDA and industry concerning the process for generic drug approvals. This confusion was dramatically underscored by FDA's publication on November 28, 1997 of a Federal Register notice announcing that "given the uncertainty created by the conflict among the courts" regarding the 180-day approval delay provision involved here, the agency was reversing a recent policy decision and would again apply the regulation overturned by the court

below "until such time as the appellate courts complete their analysis of the agency's interpretation."[3/]

Accordingly, Teva submits that the Court should at a minimum find that the district court's order is erroneous and contrary to the explicit provisions of Waxman-Hatch insofar as it fails to recognize the existence of the "flexible schedule" of alternative pathways to obtaining FDA marketing approval and prohibits FDA from making such approval effective until 180 days after the Puerto Rico patent infringement action is resolved, without regard to other alternatives.

INTEREST OF AMICUS CURIAE

Teva is primarily engaged in the business of manufacturing and marketing generic drugs. Teva also markets several "innovator" drug products under FDA-approved New Drug Applications (NDAs). Teva does not market and has no pending application to market micronized glyburide, the drug at issue in this case. However, as a generic drug manufacturer, Teva has a vital interest in the proper interpretation of the statutory provision at issue here, which is crucial to the continued viability of the generic pharmaceutical industry. If the erroneous order and incomplete reasoning of the district court are not corrected on this appeal, an important part of the comprehensive Waxman-Hatch mechanism under which Teva's generic drug applications are reviewed by FDA will be rendered unworkable, and important pathways to the approval of generic drugs

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[3/] 62 Fed. Reg. 63,269 (Nov. 28, 1997) (Attachment B).

will be blocked. This result would harm Teva's commercial interests, frustrate the Congressional purpose, and adversely affect millions of Americans, especially the elderly and the poor, whose health depends on the continued availability of lower priced generic versions of life-saving drugs.

This Brief Amicus Curiae presents a compelling statutory interpretation that has not heretofore been advocated by any of the parties in this action, and demonstrates a critical legal error in the injunction issued against the FDA by the district court.

SUMMARY OF ARGUMENT

The district court erred in one aspect of its preliminary injunction by ordering the FDA to suspend its approval of Mylan's ANDA until a date that is not early than 180 days after the date of a decision in litigation in the District Court for the District of Puerto Rico litigation holding that Mova's ANDA did not infringe Upjohn's patent. This aspect of the district court's order foreclosed alternative pathways expressly established under the Waxman-Hatch Act (specifically 21 U.S.C. §§ 355 (j)(4)(B)(iii) and (iv)), under which FDA may grant marketing approval for subsequent Paragraph IV applicants' ANDAs through mechanisms that would result in an earlier starting date for the 180 day marketing delay clock than the date upon which a judgment of non-infringement is issued in favor of the "previous applicant" in defending a patent infringement suit. This aspect of the preliminary injunction should be vacated, and on remand the district court should

be instructed that any relief entered should recognize and preserve the availability of all statutory ANDA approval pathways.

I. THE WAXMAN-HATCH PATENT CHALLENGE PROVISIONS

Waxman-Hatch implemented a carefully balanced legislative compromise between the generic and innovator segments of the pharmaceutical industry by which Congress sought to reduce the cost of health care by removing regulatory obstacles to the marketing of generic versions of drugs, while enhancing patent protection for innovators. This law established the ANDA as an expedited method to obtain FDA approval of generic versions of drugs whose patent(s) had expired, without requiring the generic manufacturer to incur the delay and expense of conducting repetitive clinical trials. In return, the law provided patent holders a regulatory method to extend the patent term of drugs for which there was undue FDA delay in approving the NDA.

To further those goals Congress created a complex system of checks and balances to reduce the potential for manipulation of the patent and regulatory processes by patent holders. A key part of that system is the so-called "Paragraph IV certification" mechanism, which is integral to this case.

A generic drug applicant may file a "Paragraph IV" certification as part of its ANDA if it believes the patent(s) covering the drug at issue to be invalid, or that its version of the drug does not infringe the patent(s). See 21 U.S.C. § 355(j)(2)(A)(vii)(IV). If such a "Paragraph IV ANDA" is filed, the applicant must also notify the patent owner by sending a "Paragraph IV notification," explaining why it believes the patent is invalid

or would not be infringed by the sale of the particular generic version at issue. The patent holder then has 45 days in which it may sue the applicant for patent infringement if it decides to do so. 21 U.S.C. § 355(j)(4)(B)(iii). If such a suit is brought within 45 days, the statute bars FDA from approving the ANDA for 30 months, or until the litigation is resolved by a ruling of patent invalidity or non-infringement, whichever is sooner. Id. Once this period elapses, or if (as happened to Mylan in this case) the patent holder does not sue within 45 days of receiving the Paragraph IV notification, FDA may approve the ANDA prior to the patent expiration date.[4/] Id.

The Paragraph IV system thus encourages direct challenges to weak patents, as well as efforts to promote the timely marketing of therapeutically equivalent drug products that do not infringe otherwise valid patents. Thus, a firm that successfully invalidates a patent (or creates a non-infringing alternative) effectuates an important statutory goal by forcing open a previously closed market for lower-priced generic equivalents to a brand name drug.

4/ Waxman-Hatch does not prohibit a patent owner which has not sued a Paragraph IV challenger within the 45 day period from later bringing a traditional patent infringement suit against the challenger, based on post-approval sale of the drug, for damages, injunctive relief, and attorney's fees. See 35 U.S.C. §§ 271(a), 281, 283 -285. Indeed, the legislative history shows that the Paragraph IV procedures were specifically crafted with this possibility in mind. See H.R. Rep. No. 98-857, Part II, 10, (Aug. 1, 1984) reprinted at 1984 U.S. Code. Cong. Adm. News 2686, 2694.

Thus, even though FDA may make approval of an ANDA effective immediately if the patent owner does not bring an action within 45 days, an applicant who actually markets its competing product without any prior judicial review of the patent runs a potentially enormous legal risk. As discussed in more detail below, an ANDA applicant therefore has strong incentives to bring a declaratory judgment action challenging the patent, so that it may seek to eliminate any potential patent infringement claims before actual marketing begins.

Patent litigation is expensive, however, and a successful Paragraph IV challenger usually opens the market not only for itself but also for other generic competitors,[5] thereby diluting the potential economic rewards for its foresight and hard work. Thus, Congress provided an additional incentive for generic manufacturers to use the Paragraph IV challenge process, by providing a 180-day delay period applicable against the approval of subsequent Paragraph IV challengers' ANDAs. This "previous challenger" incentive is at the heart of this case.

II. THE DISTRICT COURT ERRED IN FORECLOSING ALTERNATIVE STATUTORY PATHWAYS BY WHICH GENERIC DRUGS MAY OBTAIN FDA MARKETING APPROVAL

The Waxman-Hatch patent challenge provisions encourage firms to file Paragraph IV ANDAs challenging the validity or applicability of drug patents by providing a potentially valuable reward to the first such challenger for any particular drug.[6] That incentive takes the form of a 180-day mandatory delay of FDA approval of any subsequent Paragraph IV ANDA challenging the same innovator drug patent:

> (iv) If the [subsequent] application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under

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[5] Where a patent has been found invalid, any company can obtain FDA approval to sell the drug at issue upon proof that its product is therapeutically equivalent to the innovator drug. However, if a particular generic version of a drug has been found not to infringe the patent by reason of its technical characteristics, it is possible that other generic companies may not be able to compete if the non-infringing version of the drug is itself protected by patent or is otherwise unavailable to competitors.

[6] The statute does not strictly limit this incentive only to the first challenger, but rather applies the 180-day period to all ANDAs filed after a "previous application." Thus, the statute could be applied sequentially such that each subsequent challenger's approval timing is governed by the immediately preceding ANDA.

this subsection continuing[7/] such a certification, the application shall be made effective not earlier than one hundred and eighty days after --

> (I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or
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> (II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed,

whichever is earlier.

21 U.S.C. § 355 (j)(4)(B)(iv) (emphasis added).

The real issue in this case is not who is entitled to the benefits of the statutory 180-day delay of subsequent Paragraph IV ANDAs, but rather when the 180 day clock begins to run pursuant to Subclause (II), in light of the flexible schedule of multiple alternative pathways to FDA marketing approval created by that provision.

A. The District Court's Order Erroneously Closed Alternative Pathways to Marketing Approval Established by Subclause II

After Mova filed its ANDA for micronized glyburide and submitted a Paragraph IV notification, Mylan subsequently filed a Paragraph IV ANDA, and submitted a notification to Upjohn, respecting the same drug. See Mova v. Shalala, 955 F. Supp. 128, 129 (D.D.C. 1997). Upjohn sued Mova for patent infringement in the District of Puerto

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7/ Some commentators and practitioners believe the word "containing" should be substituted for "continuing" in this provision.

Rico but did not file a similar suit against Mylan. Upon the expiration of 45 days after Mylan's Paragraph IV notification, FDA approved Mylan's ANDA. Id. at 130.

Mova then sued the FDA, claiming that as the first Paragraph IV challenger for micronized glyburide, it was entitled to have FDA apply Section 355(j)(4)(B)(iv) in its favor to automatically delay approval of other ANDA applicants for this drug. FDA defended on the basis of its "successful defense" regulation, which purports to limit the applicability of the statutory approval delay provision to those situations in which the "applicant submitting the first [Paragraph IV] application has successfully defended against a suit for patent infringement" brought in response to the Paragraph IV notification. 21 C.F.R. § 314.107 (c)(1) (emphasis added).

Thus, FDA explained, because Mova (the previous Paragraph IV applicant) was still engaged (and hence had not yet "prevailed") in the Paragraph IV litigation brought by Upjohn,[8/] FDA refused to apply the 180-day statutory delay to the Mylan ANDA. Rather, FDA made Mylan's approval effective immediately upon having determined that Mylan met all other regulatory and scientific approval criteria.

The district court rejected FDA's "successful defense" regulation as contrary to the statute.[9/] According to the court:

[8/] Subsequent to the district court's decision, on December 2, 1997 the jury in the Puerto Rico case returned a special verdict of non-infringement in favor of Mova.

[9/] The "successful defense" requirement had similarly been rejected by the district court in Inwood Laboratories, Inc. v. Young, 723 F.Supp. 1523 (D.D.C. 1989), vacated as moot, No. 89-5209 (D.C. Cir., Nov. 13, 1989). However, during the course of FDA's appeal of the injunction in that case, 180 days passed without FDA acting to approve any subsequent applicant's ANDA. Thus, because the plaintiff had, de facto, received the relief demanded in its complaint, the district

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> [T]he language of the statute may be complex, and even cumbersome, but it is plain and unambiguous. It does not include a "successful defense" requirement, and indeed it does not even require the institution of patent litigation. It was Mova's first filing of an ANDA for micronized glyburide under paragraph IV, and not Upjohn's infringement suit, that required FDA to withhold approval from subsequent paragraph IV filers.

Mova, 955 F. Supp. at 130.

Although the district court was correct in overturning FDA's "successful defense" rule, it erred in formulating the remedy. The Court misinterpreted subclause (II) as permitting approval of a subsequently filed ANDA only 180 days after the date of Mova's first marketing or the date that the Puerto Rico court in the Upjohn v. Mova litigation ruled that the Upjohn patent was invalid or would not be infringed by the Mova product:

> Further Ordered that the Food and Drug Administration suspend its approval of Mylan's ANDA for micronized glyburide until a date that is not earlier than one hundred eighty days after (i) the date Mova gives notice to the Secretary of HHS that it has undertaken the first marketing of micronized glyburide under its ANDA or (ii) the date of a decision in the U.S. District Court for the District of Puerto Rico holding that U.S. Patent No. 4,916,163 is invalid or not infringed by Mova's ANDA, or until further order of this court.

955 F. Supp. 132 (emphasis added).

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court's order was vacated as moot. Now that Mova has prevailed in its Puerto Rico infringement case, the Order under review on appeal will become moot by early June 1997. Teva urges that the Court rule on the merits and not allow the uncertainties surrounding this important statutory provision to continue to evade review, as happened in the wake of the Inwood case.

This aspect of the order is erroneous because it overlooks the explicit language of Section 355(j)(4)(B)(iv) and eliminates a different statutory pathway by which the 180-day delay clock on approval of a subsequent Paragraph IV ANDA may be started.

B. The District Court Ignored the Explicit Language of Subclause II.

Section 355(j)(4)(B)(iv)(II) permits FDA approval of a subsequent ANDA effective 180 days after "a decision of a court in an action described in clause (iii)"-- that is, 21 U.S.C. § 355 (j)(4)(B)(iii). Importantly, clause (iii) "describes" two types of "actions", each of which may trigger the 180-day delay clock -- (1) a patent holder's infringement action against an ANDA applicant, and (2) a declaratory judgment action that may be brought by an ANDA applicant against the patent owner. The district court recognized the first type of action, but completely ignored the existence of the declaratory judgment action pathway, even though it is contained in the same statutory provision. This is an important omission that threatens to upset the careful balancing of rights and incentives created by Congress in Waxman-Hatch.

The clause (iii) declaratory judgment action may only be brought if the patent owner does not sue a Paragraph IV challenger within 45 days of receiving the Paragraph IV notification:

> (iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the

notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action. . . .

(I) [omitted]
(II) [omitted]
(III) [omitted]

In such an action, each of the parties shall reasonably cooperate in expediting the action. Until the expiration of forty-five days from the date the notice made under paragraph (2)(B)(i) is received, no action, may be brought under section 2201 of title 28, United States Code, for a declaratory judgment with respect to the patent. Any action brought under section 2201 shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

21 U.S.C. § 355 (j)(4)(B)(iii) (emphasis added).

Thus, the district court's order failed to recognize that a subsequent Paragraph IV applicant (such as Mylan) who is not sued by the patent owner within 45 days of its Paragraph IV notification may bring its own declaratory judgment action against the patent owner under clause (iii). Under this approach, if the court issues a declaratory judgment ruling that the patent will not be infringed by the subsequent applicant's version of the drug, or that the patent is invalid, then FDA is authorized to approve the subsequent Paragraph IV ANDA effective 180 days after such a court decision, and without regard to the status of any patent infringement action between the patent holder and the first ANDA applicant.[10/]

[10/] The declaratory judgment approach is not the only alternative pathway to starting the 180-day clock. For example, under a different FDA regulation, 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a court ruling that a patent is unenforceable also will allow FDA approval of a Paragraph IV ANDA prior to the patent expiration date. This regulation has no specific counterpart in the statute, but was

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The availability of a declaratory judgment decision as a basis for approval of subsequent Paragraph IV ANDAs is an explicit and integral part of Waxman-Hatch. Furthermore, the availability of this alternative pathway resolves many of the apparent problems that Mylan and FDA argued would result from the interpretation ultimately adopted by the district court. For example, FDA and Mylan argued that without the "successful defense" regulation, the entire patent challenge system would be rendered useless, because all subsequent challengers would be held hostage either by the first challenger losing its infringement case brought by the patent owner, or if no case was brought against the first challenger, by the first challenger choosing not to market its drug even with an approved ANDA. See 955 F. Supp. at 130-131; 21 U.S.C. § 355 (j)(4)(B)(iv)(I).

The declaratory judgment pathway provides a means for a subsequent paragraph IV applicant to avoid either of those potential roadblocks to the marketing of its generic version of the drug. By its terms, the statute allows for the possibility that the "first applicant" to file a Paragraph IV ANDA might not obtain effective approval until well after a subsequently filed Paragraph IV ANDA, particularly if the later applicant has a better factual or legal basis for its Paragraph IV certification and can more quickly

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promulgated in response to a Federal Circuit decision involving the Paragraph IV challenge procedures. See Merck & Co. Inc. v. Danbury Pharmacal, Inc., 873 F.2d 1418 (Fed. Cir. 1989).

convince a court that its product will not infringe or that the patent is invalid.[11/] This result is more likely to occur when the subsequent applicant asserts a different factual or legal basis in support of its Paragraph IV certification, such as a uniquely non-infringing formulation, of the type Mylan claims with respect to glyburide.[12/]

Moreover, because the statute allows a subsequent Paragraph IV applicant to gain FDA marketing approval effective 180 days after prevailing in its own declaratory judgment action, or in its defense of a patent owner's infringement action, "first" applicants and patent holders cannot effectively delay or manipulate the entry of other competitors' products into the market by such means as contracts among themselves to delay marketing of the generic drug covered by the first ANDA; filing frivolous Paragraph IV ANDAs for the purpose of gaining "first challenger" status; or refusing to market their drugs if not sued within 45 days by the patent owner. And, in the event a legitimate "first" applicant loses an infringement case brought by the patent owner, under the statute subsequent applicants may still prevail in cases involving the particular attributes of their product, and thereby gain FDA approval prior to patent expiration.

Congress clearly recognized the potential obstacles to rapid introduction of generic drugs if the first ANDA applicant were given a complete stranglehold over

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11/ The legislative history expressly contemplates that multiple Paragraph IV lawsuits will be consolidated in a single court, thus minimizing the risk of inequitable outcomes due to random factors such as court docket burdens and the pace of litigation. See H.R. Rep. No. 98-857, Part I, 28 (June 21, 1984) reprinted at 1984 U.S. Code. Cong. Adm. News, 2647, 2661.

12/ Other situations in which a subsequent applicant might have a different and better basis for its Paragraph IV certification could include a claim of intervening rights, see 35 U.S.C. § 252, or a valid (but disputed) claim of non-infringement by reason of license from the patent owner.

subsequent applicants. Congress addressed this problem by allowing subsequent ANDA applicants to file a declaratory judgment action which, if successful, would start the 180-day approval delay clock. The district court's order effectively blocked this explicit statutory pathway. The issue was not addressed by the parties, who were concerned with their own dispute, and not with preserving the overall effectiveness of the Waxman-Hatch mechanism.

CONCLUSION

Teva submits that the Court should affirm the preliminary injunction appealed from, but that it should vacate that portion of the injunction ordering FDA not to approve Mylan's ANDA until after a favorable decision for Mova in the Puerto Rico litigation, and that the Court should instruct the district court that any order issued on remand should, consistent with the express language of the statute, recognize and preserve all pathways to FDA approval of Paragraph IV ANDAs provided by law.

Respectfully submitted,

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January 5, 1998

Exhibit E

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ANDRX PHARMACEUTICALS, INC.,

Plaintiff,

v. Civil Action No. 98-0099 (JGP)

MICHAEL A. FRIEDMAN,
LEAD DEPUTY COMMISSIONER,
FOOD AND DRUG ADMINISTRATION, *et al.*,

Defendants.

MEMORANDUM

This matter is before the Court on plaintiff Andrx Pharmaceuticals' Motion for a Temporary Restraining Order. Plaintiff seeks an order directing the U.S. Food and Drug Administration ("FDA") to withdraw its approval of the Abbreviated New Drug Application ("ANDA") sponsored by Mylan Pharmaceuticals that it granted on March 18, 1998, and to prohibit any marketing by Mylan of its generic formulation of Dilacor XR® until April 8, 1998. The Court heard oral argument on the motion on March 26, 1998. The same day, the Court entered a temporary restraining order pending the Court's consideration of this motion and to permit Mylan Pharmaceuticals to file papers with Court.

In determining whether to grant emergency injunctive relief, the Court considers (1) the movant's likelihood of succeed on the merits, (2) whether the movant will suffer irreparable injury without such relief, (3) whether the nonmoving party or parties will suffer substantial harm, and (4) where the public interest lies. See Washington Metro. Area Transit Comm'n v. Holiday Tours, Inc., 559 F.2d 841 (D.C. Cir. 1977).

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This case raises issues regarding statutory provisions enacted in 1984 to promote the public interest in the availability of generic drugs. Specifically at issue is whether Andrx is entitled to enjoy a 180-day period of market exclusivity for its generic version of a drug, or whether FDA properly permitted another company, Mylan Pharmaceuticals, to market its generic version of the same drug prior to the running of 180 days.

In late 1995, Andrx Pharmaceuticals ("Andrx") submitted an ANDA to FDA seeking to market its generic formulation of the cardiac drug Dilacor XR® ("Dilacor"), which is patented by Jagotec AG. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Andrx certified that Jagotec AG's patent is either invalid or would not be infringed by the manufacture, use, or sale of Andrx's generic version. According to the statutory scheme, Andrx notified Jagotec (and Dilacor's manufacturer) of its ANDA filing, and was subsequently sued for patent infringement. The patent infringement suit stayed FDA's consideration and approval of Andrx's ANDA. See 21 U.S.C. § 355(j)(4)(B)(iii). On January 10, 1997, the parties settled the patent infringement case, and on October 10, 1997, FDA approved Andrx's ANDA.

During this time, Mylan Pharmaceuticals ("Mylan") also submitted an ANDA seeking to market its own generic version of Dilacor. On March 18, 1998, the FDA approved Mylan's ANDA. Andrx maintains that FDA violated 21 U.S.C. § 355(j)(4)(B)(iv)[1] by approving Mylan's ANDA. That provision reads as follows:

> If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection continuing such a certification, the application shall be made effective not

[1] The Court notes that the statute has recently been amended, so that the section referred to herein as 355(j)(4)(B) now appears at 355(j)(5)(B).

earlier than one hundred and eighty days after —

(I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or

(II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed, whichever is earlier.

Andrx argues that this provision prohibits FDA from approving Mylan's ANDA within 180 days of either (1) Andrx's initial marketing of its generic drug, or (2) a court decision holding the Dilacor patent invalid or not infringed. As there has been no court order holding the Dilacor patent invalid or not infringed, Andrx maintains that FDA cannot approve Mylan's ANDA until 180 days from when Andrx began marketing its generic version of Dilacor, or April 8, 1998.

FDA responds that it approved Mylan's ANDA pursuant to a regulation issued by FDA to implement the statutory provisions at issue. The specific regulation at issues is 21 C.F.R. § 314.107(c)(1), which conditions the 180-day period of exclusivity on the requirement that " the applicant submitting the first application has successfully defended against a suit for patent infringement . . . ." Thus, under FDA's regulation, in order to receive the 180-day period of exclusivity, an ANDA applicant must (1) be the first to file a paragraph IV certification, (2) be sued, and (3) successfully defend the patent infringement suit. Pursuant to this regulation, Andrx is not entitled to the 180-day period of exclusivity, and thus the approval of Mylan's ANDA was permissible, because Andrx has not "successfully defended" a patent infringement suit. Rather, Andrx settled the patent infringement suit and that settlement did not include a finding that the patent was invalid or not infringed.[2]

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[2] FDA states that a settlement of a patent suit may qualify as a "successful defense" when entry of the final judgment includes a finding that the patent is invalid or not infringed. Government Opposition at 7 n.3.

FDA maintains that the statute is ambiguous and that its interpretation is due deference because it is reasonable and consistent with the purposes of the statute. FDA argues that "the statute does not specifically address whether the exclusivity period prohibits FDA's approval of other paragraph IV ANDA applicants if the first filer is sued for patent infringement and loses, settles, or if it is not sued at all," and that "[t]hus, FDA was required to fill the gap . . . ." The Court does not agree.

The statute provides two alternative triggering dates for the running of the 180-day period: (1) the initial marketing of the prior ANDA applicant's generic drug, or (2) a court finding that the patent is not valid or not infringed. The latter alternative clearly requires the filing of a patent suit against the initial generic manufacturer.[3] The former does not. FDA's argument that the statue does not speak to whether the 180 days should run if the first ANDA applicant is never sued, is sued and settles, or is sued and loses, is not persuasive. The statue is clear, in those circumstances, the 180-day period begins to run from the initial marketing of the drug. There is simply no requirement in the statute that the first ANDA applicant must be sued. Because the statute is clear, there is no need to defer to FDA's regulatory interpretation under Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 842-43, 104 S. Ct. 2778, 2781-82 (1984) (requiring deference to an agency interpretation if Congress has not "directly spoken to the precise question at issue" and if the agency interpretation is reasonable).

Two other judges of this Court have held against FDA on this precise issue, holding that the statute is not ambiguous. In Mova Pharmaceutical Corp. v. Shalala, 955 F. Supp. 128

[3] In fact, by its terms the second alternative requires a suit for patent infringement pursuant to section 355(j)(4)(B)(iii).

(D.D.C. Jan. 23, 1997), appeal pend'g, Nos. 97-5082, 97-5111, Judge Robertson, discussing the provision at issue here, held that Chevron deference was not required because "the statute is neither 'silent [n]or ambiguous.'" Id. at 130 (alteration in original). The court further held that "[t]he language of the statute may be complex, and even cumbersome, but it is plain and unambiguous. It does not include a 'successful defense' requirement, and indeed it does not even require the institution of patent litigation." Id.; see also Inwood Laboratories, Inc. v. Young, 723 F. Supp. 1523, 1526 (D.D.C. 1989) ("Section 355(j)(4)(B)(iv) explicitly provides that a primary generic manufacturer may qualify for the 180 day exclusivity in one of two ways--by compliance with subpart I or by compliance with subpart II. . . . The two alternatives are clear, and they establish a complete and workable statutory scheme. . . . There is no ambiguity in the provisions of subpart I that requires the Court or permits the FDA to read into it a requirement of a lawsuit which is simply not there."), vacated as moot, 43 F.3d 712 (D.C. Cir. 1989).

The parties have provided the Court with an order entered by the District Court for the Eastern District of North Carolina which purportedly holds contrary to the courts in this district. See Granutec, Inc. v. Shalala, No. 97-cv- 485, (Order dated July 3, 1997). The court in that case determined that pursuant to its regulation, FDA was required to approve an ANDA to a second applicant because the first applicant had not "successfully defended" a patent suit. Id. at 3. In Granutec, however, the court did not address the conflict between the statute and the regulation.

It is apparent to the Court that both FDA and the intervenor seem concerned not so much about ambiguity as about what it considers unfavorable results of applying the clear statutory language. These potential scenarios do trouble the Court. However the Court also notes that perverse results could obtain from permitting FDA to follow its regulation. For example, the

circumstances presented to the court in Mova were that the first ANDA applicant was tied up in patent litigation and had never gone to market, thus had had no benefit of the 180-day period of exclusivity, at the time FDA approved the second ANDA. This too is a result seemingly inconsistent with a statutory provision intended to reward the first ANDA applicant for risks associated with being the first generic drug to seek FDA approval. Other, similarly troublesome, situations may also result. See Inwood, 723 F. Supp. at 1526-27 (discussing possible outcomes of applying FDA regulation).[4]

In light of these facts, the Court finds that Andrx has demonstrated a strong likelihood of success on the merits.

The Court further finds that Andrx would be harmed by not receiving the full benefit of the 180-day period of market exclusivity to which it is entitled. Although the period of time at issue is rather short, all parties agree that the industry in which Andrx competes is exceedingly competitive and that each day on the market is worth a large amount of money. Moreover, what is at issue is not simply money, but market share. The Court further notes that where, as here, the likelihood of success on the merits is strong, a lesser showing of irreparable injury is required to obtain relief. See, e.g., Mova, 955 F. Supp. at 131 (citing Cuomo v. United States Nuclear Regulatory Comm'n, 772 F.2d 972, 974 (D.C. Cir. 1985) (per curiam)).

The intervenor vigorously argues that it will be substantially harmed by the entry of an

---

[4] In Inwood, the court noted, for instance, that "[u]nder the FDA's interpretation, if the patent holder chooses to sue only the second, the third, or the fifth applicant, the rather bizarre result will be that no one is entitled to exclusivity." 723 F. Supp. at 1526. The court further noted that "[b]y subjecting the exclusivity entitlement to the caprices of the patent holder, the FDA's interpretation would seem to affect adversely the incentives that Congress sought to create in providing for 180 days of exclusivity for the manufacturers of generic drugs." Id. at 1527.

order prohibiting them from marketing their product until April 8, 1998. Specifically, Mylan argues that it stands to lose $1.6 million and will suffer harm to its reputation because it will have to renege on promises to ship orders "immediately". Mylan's Opposition at 10-11. However, because the Court has found that it is likely that Mylan's ANDA should not have been granted until April 8, the "harm" to which Mylan refers amounts primarily to losing what it should never have had — the opportunity to market and sell its product from March 18 to April 8. Although there may be other harm to Mylan—such as delayed shipment of orders already placed--the Court finds that the balance of the factors weigh in favor of granting a temporary restraining order.

Finally, the Court finds that the public interest in the faithful application of the statute outweighs the public interest in making Mylan's generic drug available nine days earlier.

For the foregoing reasons, the Court will enter an appropriate order directing Mylan to cease the marketing, sale, and distribution of its generic version of Dilacor until April 8, 1998. Although Andrx requested an order directing the FDA to withdraw its approval of Mylan's ANDA, the Court finds that such an order could compound the harm to Mylan by calling into question the action already taken by Mylan in reliance on FDA's action. Thus, and since Mylan is now a party to this action, the Court will address its order directly to Mylan.

The Court will also order that Andrx post a bond in the amount of $500,000.

Date: MAR 30 1998

JOHN GARRETT PENN
United States District Judge

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FILED

MAR 30 1998

NANCY MAYER-WHITTINGTON, CLERK
U.S. DISTRICT COURT

ANDRX PHARMACEUTICALS, INC.,

Plaintiff,

v. Civil Action No. 98-0099 (JGP)

MICHAEL A. FRIEDMAN,
LEAD DEPUTY COMMISSIONER,
FOOD AND DRUG ADMINISTRATION, *et al.*,

Defendants.

ORDER

This matter is before the Court on plaintiff Andrx Pharmaceuticals' Motion for a Temporary Restraining Order. For the reasons set forth in the accompanying memorandum, it is hereby

ORDERED that plaintiff's Motion for a Temporary Restraining Order is granted, and it is further

ORDERED that Intervenor Mylan Pharmaceuticals cease the marketing, sale, and distribution of its generic version of Dilacor XR® until April 8, 1998, and it is further

ORDERED that Andrx Pharmaceuticals must post a bond in the amount of $500,000.

Date: MAR 30 1998
5:30 PM

JOHN GARRETT PENN
United States District Judge

(N)

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Exhibit F

LITIGATION

New York Law Journal

Monday, February 22, 1999

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Litigating Drug Approvals

Patent Owners, Generic Manufacturers Go to Court

BY CHARLES GUTTMAN AND JEFFREY J. MACEL

In 1984 Congress passed the Drug Competition and Patent Term Restoration Act (Hatch-Waxman Act, or Act) to make "available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962."[1] The history and purpose of the Act are thoroughly discussed in case law.[2]

The Act provides an expedited procedure for approval of a generic version of an approved drug by permitting generic manufacturers to file with the Food and Drug Administration (FDA) an Abbreviated New Drug Application (ANDA) in lieu of filing a more extensive New Drug Application (NDA).[3] In order for an ANDA to be approved, the ANDA applicant may rely on the safety and effectiveness studies submitted by the pioneer applicant in the NDA, and must only establish that the proposed generic version of the drug is the "bioequivalent" of the already-approved drug.[4]

The Act also permits the generic manufacturer to conduct development and testing of patented drugs without infringing the patents applicable to the drug.[5] The Act further provides for a restoration of a portion of the patent term on drugs for the period while they were awaiting approval from the FDA.[6]

Prior to passage of the Act, the owners of patents and innovators of drug technology (Innovators) wanted an extension of the term of their patents because it usually took several years after the successful prosecution of a patent on a drug to receive FDA approval and to begin marketing of the drug. On the other hand, the competitors (Generics), who provide low-price alternatives to the Innovators' drugs, desired a simplified process for gaining FDA approval of a generic version of an already-approved drug. The Generics also pressed Congress to amend the patent statute to overturn a decision of the Court of Appeals for the Federal Circuit that declared it an act of patent infringement for Generics to conduct tests with a patented drug during the term of the patent in order to submit test data to the FDA.

The resulting legislation struck a compromise; it balanced the rights of the Innovators against the public policy of making generic drugs more available by easing the FDA approval process for Generics. The Act also provided a novel statutory scheme for dealing with the patents that the Innovators had obtained on approved drugs. The Act permits the Innovators to list the applicable patents in a publication of the FDA commonly known as the "Orange Book." The Act requires the ANDA to contain a certification that the generic drug will not infringe these patents because:

(I) there are no patents listed in the Orange Book,

(II) the patents have expired,

(III) approval to market is not de sired until the patents expire, or

(IV) the patents are invalid or will not be infringed by the manufacture, use, or sale of the drug for which approval is being sought (a so-called "paragraph IV certification").[7]

Although ANDAs filed with a paragraph I or II certification can be approved by the FDA immediately, and an ANDA with a paragraph III certification may be approved by the FDA at the expiration of the patent, an ANDA filed with a paragraph IV certification provides the patent holder with an automatic cause of action for patent infringement.[8] The ANDA filer must give notice to the owner of the patents that an ANDA has been filed containing a paragraph IV certification.[9] The ANDA filer also must set forth in the notice letter the factual and legal basis for its claim that the applicable patents are invalid and/or not infringed.[10] The Act provides that after receiving the notice letter, the patent owner may bring suit for patent infringement against the ANDA filer within 45 days.[11]

The Act establishes that the filing of an ANDA containing a para-

Charles Guttman is a partner in the New York office of [illegible] and a [illegible] patent attorney. Jeffrey J. Macel

Continued from page S1

For this technical act of infringement, the Innovator is provided with statutorily proscribed remedies.[3] If the Innovator does not respond or file suit within 45 days of receiving the notice letter, the FDA may approve the Generic's ANDA immediately and the Generic may commence marketing once the ANDA is approved.

However, if the Innovator files suit within 45 days, the Act provides that the FDA may not approve the ANDA until either (1) 30 months from the filing of the infringement suit has passed, or (2) the underlying patent infringement suit commenced by the Innovator terminates in favor of the Generic.[4] As a practical matter, Innovators almost always file suit within the 45-day window because the Act provides what amounts to a preliminary injunction, preventing the Generic from marketing its product for 30 months.

Litigating Drug Approvals

As an inducement to remove invalid patents from the Orange Book, the Act provides a 180-day exclusive marketing period to the first ANDA filer with a paragraph IV certification. During this exclusivity period, the Innovator and first ANDA filer with a paragraph IV certification are the only manufacturers permitted to market the drug in the United States. It is estimated that the Generic awarded the 180-day exclusivity books approximately 40-50 percent of all generic sales even after other Generics are permitted to enter the market. Thus, the 180-day exclusivity period is a substantial incentive for Generics to be the first ANDA filer with a paragraph IV certification.

Resulting Litigation

Given the benefits attendant with being the first ANDA filer, disputes over who is entitled to the 180-day exclusivity have generated an inordinate amount of litigation. The primary issues in this litigation are (1) who is entitled to the exclusivity and (2) when it begins to run.

According to the language of the Act, the exclusivity is awarded to the first ANDA filer (1) when the Secretary of the FDA receives notice "of the first commercial marketing of the drug" or on (II) "the date of a decision of a court in an action ... holding the patent which is the subject of the certification to be invalid or not infringed, whichever is earlier."[5] Initially, the FDA adopted a regulation awarding the 180-day exclusivity period to the first ANDA filer with a paragraph IV certification which (1) began to commercially market its generic product or (2) successfully defended the patent infringement suit brought by the Innovator (the "successful defense trigger").[6]

In *Mova Pharmaceutical Corp. v. Shalala*, the Court of Appeals for the District of Columbia held that the "FDA exceeded its statutory authority in imposing the successful defense requirement as a prerequisite to the invocation of the 180-day exclusivity rule by a first applicant . . ."[7] The *Mova* court reasoned that the "successful defense requirement" does not appear in the statutory text. Moreover, the court found that it was neither justified by a need to protect the essential function of the statute, nor derived from clear congressional intent.

Mova involved a complicated factual scenario which underscores the complex nature of the statute and its interrelation with patent law and the FDA's approval process. Mova Pharmaceutical filed an ANDA with a paragraph IV certification to manufacture a generic version of glyburide, a drug patented by Upjohn and still under term. Within the 45-day window, Upjohn sued Mova, alleging that Mova's product infringed Upjohn's patent.

Shortly thereafter, Mylan Pharmaceutical filed an ANDA with a paragraph IV certification for the same drug. Upjohn did not sue Mylan and the FDA approved Mylan's ANDA, effective immediately, as of Dec. 19, 1996, while Upjohn's suit against Mova was still pending.

On Dec. 26, 1996, upon discovering that the FDA had approved Mylan's ANDA, Mova brought suit against the FDA in the District Court for the District of Columbia. Mova requested a preliminary injunction to compel the FDA to delay its immediate approval of Mylan's ANDA. Mova argued that it was entitled to the 180-day exclusivity starting from the conclusion of its patent litigation with Upjohn, or from the time when Mova began to commercially market its product, neither of which had occurred.

Mova also argued that the FDA could not approve Mylan's ANDA because neither of these events had occurred. The FDA contended that Mova was not entitled to the 180-day exclusivity because it had not yet commercially marketed the drug in question, or successfully complete its litigation with Upjohn, as required by the FDA regulation.

The district court agreed with Mova and granted a preliminary injunction barring the FDA from enforcing its rule containing the successful defense requirement, and effectively reversing the FDA's immediate approval of Mylan's ANDA. The appellate court affirmed the grant of the preliminary injunction and held that the FDA had exceeded its statutory authority in imposing the successful defense requirement as a prerequisite to the 180-day exclusivity period. The court gave a literal interpretation to the statute, which did not include a successful defense requirement.

The *Mova* court emphasized the strategic differences in interpreting the statute with and without the successful defense requirement as required by the FDA regulation. The court noted that the successful defense requirement "permits later applications to be approved even though neither trigger has been satisfied, simply because the first applicant's litigation has not yet come to a successful conclusion."[8]

Therefore, in essence, the successful defense requirement subverts the "commercial-marketing trigger" because it has the practical effect of preventing successive applicants from gaining approval until the conclusion of the pending litigation, while preventing the first applicant from enjoying the exclusivity period if it was never sued. The *Mova* court concluded that such a result was inconsistent with the purpose and language of the statute, and therefore determined that the FDA had exceeded its authority in adopting the successful defense requirement in its regulation.[9]

The practical effect of the *Mova* decision is that only Mova Pharmaceutical could be awarded the exclusivity period because it was the first ANDA filer, and other Generics

Litigating Drug Approvals

Continued from page S10

could not begin to market a generic until at least 180 days after Mova began to commercially market a generic version of the drug, or successfully concluded its litigation with Upjohn. Although Mova could begin to market its product 30 months after the lawsuit was instituted, given the potential liability, it is regarded as common practice not to commence marketing while an infringement action is pending.

Thus, although Mylan had not been sued for infringement, the FDA was precluded by the statute from approving its ANDA until one of the triggers began the 180-day period. As long as the *Mova* suit was not resolved favorably for Mova, and as long as Mova did not begin to commercially market its product, neither Mylan nor any other Generic could gain FDA approval to market this product.

When Generic Not Sued

The *Mova* case involved a situation where the first ANDA filer with a paragraph IV certification had been sued, but it had not yet won the suit and had not yet begun commercial marketing of the drug. After *Mova*, the issue arose as to whether the 180-day exclusivity could be awarded to a Generic which was not sued for patent infringement.

Under an interim rule adopted by the FDA, this was no longer a requirement to be awarded the 180-day exclusivity.

In June of 1998, the FDA issued a formal position statement[20] declaring that it would no longer apply the successful defense provision of its regulations. The FDA stated that it would follow the statute as interpreted by *Mova*. In November of 1998, the FDA published an interim rule in the Federal Register that deleted the "successful defense" portion of 21 C.F.R. §314.107 (c).[21]

The interim rule removed both the requirement that a Generic successfully defend the underlying patent infringement suit, and the requirement that it actually be sued. In another lawsuit, the interim rule was contested on the ground that the FDA went beyond the mandate of *Mova* in deleting the requirement that the first ANDA filer be sued.

In *Purepac Pharm. Co. v. Friedman, M.D.*,[22] the Court of Appeals for the District of Columbia reaffirmed its decision in *Mova*, clarifying that the first ANDA filer with a paragraph IV certification is the party entitled to the exclusivity period. Furthermore, in accordance with *Mova*, the *Purepac* court reiterated that the exclusivity period will not begin to run until the first filer who is entitled to it either commercially markets the drug or successfully concludes the patent litigation.

The *Purepac* court also endorsed the FDA's interim rule removing the requirement that the ANDA applicant be sued to be entitled to the exclusivity period. Under the interim rule, the first to file an ANDA with a paragraph IV certification is entitled to the 180-day exclusivity, regardless of whether it is sued. Furthermore, the 180-day exclusivity only begins to run when this first ANDA filer begins to commercially market the product or successfully concludes its lawsuit.

Conclusion

Although this recent litigation has provided some answers to the basic questions of who gets the exclusivity period and when it begins to run, the FDA has been receiving comments for the promulgation of a new rule. The current state of affairs with regard to the FDA's inability to approve the application of successive ANDA filers has raised concerns about potential collusion between the first ANDA filer and the innovator. If the first ANDA filer never begins marketing its product and enters into a settlement with the innovator so that it does not successfully conclude its lawsuit, successive ANDAs cannot be approved, and a generic version of the product cannot be brought to market until after the patent expires.

In both *Mova* and *Purepac*, the court suggested that the FDA could address such problems by limiting the time in which the 180-day exclusivity could be exercised by a first ANDA filer who is not sued. Barring a change in the rules, reversal of the recent case law or Congressional amendment of the statute, these issues remain a cause for concern.

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(1) 21 U.S.C. §355(j) (1994).
(2) See, e.g., *Eli Lilly & Co. v. Medtronic Inc.*, 496 U.S. 661 (1990); *Bristol-Myers Squibb v. Roxane Lab.*, 69 F.3d 1130 (Fed. Cir. 1995), cert. denied, 516 U.S. 1026 (1995); *Abbott Laboratories v. Zenith Lab. Inc.*, 934 F. Supp. 945 (N.D. Ill. 1995).
(3) 21 U.S.C. §355(j) (1994).
(4) 21 U.S.C. §355(j)(2)(A)(iv) (1988).
(5) 35 U.S.C. §271(e)(1) (1988).
(6) 35 U.S.C. §156 (1994).
(7) 21 U.S.C. §355(j)(5)(B)(iii) - (IV) (1988).
(8) 21 U.S.C. §§355(j)(5)(B)(i)-(iv) (1988); 35 U.S.C. §217(a)(2) (1994).
(9) 21 U.S.C. §§355(b)(3)(A), 355(j)(2)(A)(vii)(I) (1988).
(10) 21 U.S.C. §§355(b)(3)(B), 355(j)(2)(A)(vii)(II) (1988).
(11) 21 U.S.C. §355(c)(3)(D) (1988).
(12) 35 U.S.C. §271(e)(2) (1988).
(13) 35 U.S.C. §271(e)(4) (1988).
(14) 21 U.S.C. §§355(j)(5)(B)(iii), 355(j)(5)(D)(i)(I) (1988).
(15) 21 U.S.C. §355(j)(5)(B)(iv) (1988).
(16) 21 C.F.R. §314.107(c)(1). See Note 21, *infra*, for modification.
(17) *Mova*, 140 F.3d 1060, 1076 (D.C. Cir. 1998). In an unpublished opinion, the Fourth Circuit held, 18 days prior to the *Mova* opinion, that the FDA had exceeded its authority in imposing a successful defense requirement. See *Granutec Inc. v. Shalala*, Nos. 97-1823, 97-1874, slip op. at 13-14, 1998 WL 153418 (4th Cir. Apr. 3, 1998).
(18) Id. at 1063.
(19) Id. at 1076.
(20) Guidance for Industry, 180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act, June 1998.
(21) The FDA's amendment to 21 C.F.R. §314.107 deletes the provision of the rule that states "and the applicant submitting the first application has successfully defended against a suit for patent infringement brought within 45 days of the patent owner's receipt of notice submitted under 21 C.F.R. § 314.52." See 63 Fed. Reg. 59,710, 59,712 (1998).
(22) *Purepac*, 162 F.3d 1224 (D.C. Cir. 1998).

Uniform Standards Act of 1998

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As Professor Coffee pointed out, initial public offerings by companies whose stocks are traded on bulletin boards, the pink sheets or NASDAQ's "small cap" market are not covered by the Standards Act. This would seem to provide a major impetus for such companies to list their shares on an exchange and thus receive the benefits of the Standards Act.

Time Will Tell

Like any legislation, the Standards Act is not perfect. Its goals, however — to restrict [illegible] class actions are [illegible] — appear to be laudable.

Of course, it is questionable what impact these reforms actually have had on securities class actions. Statistics do not indicate, for instance, that there are substantially fewer securities class actions, and thus it is not clear that there are now far fewer frivolous actions. Only time will tell whether the expense of the 1995 Act and the Standards Act, such as litigating the meaning of all of the new provisions and the potential loss of some legitimate claims, was worthwhile.

Inside Washington's

FDA Week

an exclusive weekly report on Food and Drug Administration policy, regulation and enforcement

Vol. 7, No. 21 — May 25, 2001

CUSTOMS ASKS FDA TO PRE-APPROVE PURCHASES OF FOREIGN DRUGS

The U.S Customs Service has recommended FDA pre-approve U.S. citizens' purchases of a drug imported from a foreign country via mail, or install a digital monitoring program in foreign mail facilities at FDA's expense to cut back on the importation of illicit pharmaceuticals. Customs is also asking for FDA to provide more detailed guidance regarding what pharmaceuticals should be kept from entering the United States. FDA's drug personal use exemption policy has posed a major headache for an "overwhelmed" Customs — which at one point last year was so fed up with the huge influx of pharmaceuticals that it threatened to dump all pharmaceutical parcels at local FDA offices.

Under the Food, Drug and Cosmetic Act, it is currently illegal for parties other than manufacturers to import

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In effort to protect population from vCJD
FDA LIKELY TO MOVE TOWARD STRICTER BLOOD DONOR DEFERRAL POLICY

On the heels of a major American Red Cross announcement that starting in mid-September it will refuse blood donations from persons who lived in Europe for six months since 1980, FDA is considering recommending similar restrictions to protect against the theoretical risk of spreading new variant Creutzfeldt-Jakob Disease (vCJD), an informed source says. The likelihood of an FDA guidance document is prompting concerns among other blood banking groups that such restrictions could lead to a 10 percent decrease in an already scarce blood supply.

FDA's biologics center chief Kathryn Zoon recently met with officials from the American Red Cross to discuss deferral issues, but at press time the agency had not yet responded to *FDA Week* inquiries as to the out-

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USP TACKLES ANCILLARY PRODUCT ISSUES AS FDA STRUGGLES TO REGULATE

The United States Pharmacopeia (USP) is attempting to tackle the tricky task of setting quality standards for ancillary products at a time when FDA is struggling with how to regulate in the area. First, USP hopes to add general chapters on ancillary products to its compendium, according to a USP source, and then the organization will move onto producing ancillary product monographs — which are basically recipes with quality standards.

Ancillary products are components used during manufacturing that should not be present in the final product. FDA is currently struggling with which center — biologics or devices — should take the lead in the review and approval of various categories of these products (see *FDA Week*, Feb. 16, p1). FDA is also on difficult footing in regulating these products as, by definition, they are not present in the end result of the manufactured product.

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Old labeling may not be appropriate, but new labeling protected
FDA GENERIC DRUG OFFICE GRAPPLES WITH PEDIATRIC LABELING ISSUE

FDA's generic drug office is trying to come to grips with pediatric labeling resulting from studies conducted under the FDA Modernization Act (FDAMA) pediatric exclusivity provision that rewards brand-name drug companies with an additional six months of patent life in exchange for performing pediatric studies. The existing labeling may not be appropriate for generic versions of drugs, but generic drug companies are blocked from using the new labeling because such labeling is protected by three years of exclusivity under the Hatch-Waxman amendments.

Gary Buehler, acting director of the Office of Generic Drugs, discussed the issue at this week's FDA/Generic

No longer automatically put into the queue

OGD MAY REFUSE TO FILE NEW STRENGTH AMENDMENTS, ANDA SUPPLEMENTS

In what one drug industry source calls a major development and grounds for legal debate, FDA's Office of Generic Drugs (OGD) plans to require supplements and amendments to abbreviated new drug applications (ANDAs) for new strengths to meet the same filing requirements as original ANDAs. Until now ANDA amendments and supplements for new strengths have been allowed to evade the preliminary review OGD's Review Support Branch performs before deciding whether to file an ANDA. But this will no longer be the case, as the branch will review and potentially refuse to receive shoddy or incomplete amendments and supplements for new strengths, an OGD official said this week.

An industry source characterizes OGD's plan to start reviewing amendments and supplements seeking a new strength as "a big deal." The source warns that the agency is on shaky legal ground, and could be challenged in court if it actually decides to refuse to receive an amendment or a supplement for a new strength, as there is no regulatory provision for conducting such a preliminary review on amendments and supplements.

Gregory Davis, branch chief of the Review Support Branch under OGD's Division of Labeling and Program Support, spoke of the branch's decision to require such preliminary reviews at this week's FDA/Generic Pharmaceutical Association (GPhA) workshop concerning regulatory issues on generic pharmaceuticals.

Under the regulatory scheme established for generic drugs, an application must contain sufficient information to allow OGD to conduct a review in an efficient and timely manner. Upon receipt of the application, a project manager within the Regulatory Support Branch performs a pre-filing assessment of the ANDA's completeness and acceptability.

If this initial review shows that the application contains all the necessary components, an acknowledgment letter is sent to the applicant with confirmation of the filing date. But if the application is missing one or more essential components, FDA will send a refuse to file letter to the sponsor. The letter outlines what is missing from the application and informs the sponsor that the ANDA will not be filed until the application is complete. Review of that application will be put on hold until the applicant provides the requested data and FDA signs off on the application.

Davis explained that the agency has had a problem recently with new strengths. Unlike original ANDAs, amendments and supplements do not have to undergo an initial review. New strengths are eligible for 180-day exclusivity. In order to receive 180-day exclusivity the sponsor has to be the first to file. In the race to receive 180-day exclusivity, applicants anxious to receive exclusivity for a new strength have been submitting the new strength as an amendment or supplement to an ANDA instead of as part of an original ANDA, thereby avoiding the initial review. Applicants have been sending in shoddy and incomplete supplements and amendments that would not have been received if they had been submitted as original ANDAs, Davis complained.

Davis intends to put a stop to this practice. The Regulatory Support Branch will perform preliminary reviews of all new strengths, and any deficiencies in an amendment or supplement for a new strength will result in a telephone call or a refusal to receive. Davis also announced that new strength amendments require a new patent certification and new notification to the brand-name company.

Other refuse to receive issues, according to Davis, include problems with inactive ingredients, failed bioequivalence studies where the cover letters to the applications actually state that the bioequivalence study failed, sterility assurance and filter validation, no dissolution data, problems with Drug Master File authorization and stability with less than four accelerated data points.

FDA PUTS FINAL 180-DAY GENERIC DRUG EXCLUSIVITY RULE ON HOLD

FDA announced this week that the agency is putting publication of its final rule on generic drug 180-day exclusivity on hold in light of recent court cases and the reintroduction of the Greater Access to Affordable Pharmaceuticals (GAAP) Act, which would reform the Hatch-Waxman amendments in order to cut down on anti-competitive practices engaged in by brand-name drug companies to keep generic drugs off the market.

Gregg Davis, branch chief of the Review Support Branch, Division of Labeling and Program Support at the Office of Generic Drugs, informed this week's FDA/Generic Pharmaceutical Association (GPhA) workshop regarding regulatory issues on generic pharmaceuticals that the final rule is on hold due to recent court cases and the recent reintroduction of GAAP. There is no time frame at present for issuing the rule, asserted Davis.

The final rule will amend regulations governing 180-day generic drug exclusivity to clarify existing eligibility requirements and conditions for abbreviated new drug application sponsors, will modify current eligibility requirements and impose new eligibility conditions. The revisions are the result of recent court decisions including *Mova Pharmaceutical* v. *Shalala*, which struck down the agency's "successful defense" provisions under which a generic applicant had to be sued by the innovator and successfully argue the case in order to receive the exclusivity.

An industry source is not surprised that the final rule is on hold, as there are a number of developments that directly bear on the agency's interpretation of the statute, including recent court rulings on buspirone and

Exhibit G

nifedipine. In *Mylan Pharmaceuticals v. Tommy Thompson*, Judge Fredrick Stamp of the U.S. District Court for the Northern District of West Virginia denied Mylan's motion for a preliminary injunction and temporary restraining order against the agency's Feb. 6, 2001 decision granting Teva Pharmaceuticals USA's citizen petition that allowed a Biovail version of Procardia to come to market. Teva is the marketing arm for Biovail. Mylan is appealing the decision (see *FDA Week*, April 27, p6). Also pending is Bristol-Myers Squibb's appeal of a court ruling forcing it to delist its late-developed patent for a metabolite of buspirone from the Orange Book.

There are also legislative developments waiting in the wings. At the beginning of this month Sens. Charles Schumer (D-NY) and John McCain (R-AZ) reintroduced a tweaked version of GAAP. The revised version would strike the 30-month stay during which FDA cannot approve an abbreviated new drug application (ANDA); beef up rolling 180-day exclusivity; specify that generics have the right to seek declaratory judgment against the brand-name company; and would restore part of *Mova* by requiring generics to be involved in litigation with the innovator company (see *FDA Week*, May 4, p5).

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FDA-approved drugs. But FDA has long had a personal use exemption policy that was originally designed to let patients access life-saving therapies at a time when the United States was often not the first country to approve a drug – and FDA has opted to use its enforcement discretion in deciding what imports fall under the exemption.

The regulation of prescription pharmaceuticals coming in via mail is an area where neither FDA nor Customs wants responsibility. FDA's human resources and funding resources are stretched thin, and Customs argues that it has neither the expertise nor the authority to determine what prescription pharmaceuticals should be allowed into U.S. commerce.

The issue has been heating up in preparation for an upcoming House Energy and Commerce oversight and investigations subcommittee hearing on drug imports, originally scheduled for May 24. The hearing has been postponed to make way for the committee's deliberations on President Bush's energy proposal, but will be held on June 7. At the hearing, the House subcommittee is expected to press FDA on what it is doing to address the massive influx of pharmaceuticals that come into the United States.

Benjamin England, regulatory counsel to the associate commissioner for regulatory affairs at FDA's Office of Regulatory Affairs, told attendees of this week's FDA/Generic Pharmaceutical Association (GPhA) workshop regarding regulatory issues on generic pharmaceuticals that Customs recently sent letters to FDA asking it to clarify its personal use exemption policy.

England announced that FDA is floating proposals on better ways to handle the personal use exemption, and is eying both drugs that are physically brought in by individuals traveling across the border as well as those that enter the country via mail order. FDA, said England, is considering trying to educate consumers about the potential risk of buying drugs outside the United States. FDA is also considering increasing the enforcement of mail importation, maintained England.

Customs wrote the agency a series of letters asking for clarification on how to implement the agency's personal use exemption policy. A Customs source says the letters were searching for specific guidance on what to hold and what not to hold at the border. FDA has essentially taken the stance that decisions should be made on a case-by-case basis, says the Customs source. But Customs has neither the authority nor the expertise to independently determine which prescription pharmaceutical products should be allowed in the country, maintains the source, unless they pose a Customs violation or a violation of Drug Enforcement Agency laws. For instance if a package is labeled as clothing but an x-ray reveals the package actually contains pharmaceuticals, Customs will hold the package. But otherwise Customs is ill-equipped to make those decisions, and FDA personnel do not work full time at the mail facilities

Customs is looking for specific criteria that will narrow the universe of what Customs could accept. For example, the agency might go back to the original intent of the exemption and demand that only drugs unapproved in the United States be permitted. FDA could compile a list of drugs approved in the United States, and Customs would be able to refer to that list.

Customs Commissioner Raymond Kelly sent a Jan. 6, 2000 letter to former FDA Commissioner Jane Henney asking for guidance as to what packages containing pharmaceuticals it should hold and what it could release. Customs urged the agency to provide "written national standards" it could use to identify pharmaceutical products subject to FDA review, according to an informed source.

In a Feb. 18 response, says the source, Henney responded that FDA would be more than happy to meet with Customs to discuss the issues raised in the letter. In an Aug. 11, 2000 meeting FDA and Customs met and decided to convene a joint Customs/FDA task force to establish a pilot program geared at determining the extent of the